FA04.00

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001

1. Name and Address of Registrant (include ZIP Code)

ZIP CODE

2. Phone No. (Include Area Code)

3. DEA Registration Number
2 ltr. prefix | 7 digit suffix

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (Specify)

6. County in which Registrant is located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 ☐ Night break-in
2 ☐ Armed robbery
3 ☐ Employee pilferage
4 ☐ Customer theft
5 ☐ Other (Explain)
6 ☐ Lost in transit (Complete Item 14)

11. If Armed Robbery, was anyone:
Killed? ☐ No ☐ Yes (How many) _____
Injured? ☐ No ☐ Yes (How many) _____

12. Purchase value to registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer?
☐ Yes ☐ No

E. If received, did it appear to be tampered with?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past?
☐ No ☐ Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a ly valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 30 minutes per response , including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FORM DEA - 106 (11-00) *Previous editions obsolete*

CONTINUE ON REVERSE

FORM DEA-106 (Nov. 2000) Pg. 2

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
Examples: Desoxyn	Methamphetamine Hydrochloride	5 mg Tablets	3 x 100
Demerol	Meperidine Hydrochloride	50 mg/ml Vial	5 x 30 ml
Robitussin A-C	Codeine Phosphate	2 mg/cc Liquid	12 Pints
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
[redacted]			
26.			
27.			
28.			
29.			
30.			
31.			
32.			
33.			
34.			
35.			
36.			
37.			
38.			
39.			
40.			
41.			
42.			
43.			
44.			
45.			
46.			
47.			
48.			
49.			
[redacted]			

I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature _____ Title _____ Date _____

FOIA Confidential Treatment Requested By Cardinal

CAH 022125

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

Note: Only submit reports to the agency in the state in which your facility is located

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
ALABAMA	STATE BOARD OF PHARMACY (336) 206-5666	YES	YES	NO
ALASKA	STATE BOARD OF PHARMACY (907) 465-2589	YES	NO	NO
ARIZONA	STATE BOARD OF PHARMACY (623) 463-2727	YES	YES	YES
ARKANSAS	STATE BOARD OF PHARMACY (501) 682-0190	YES	NO	NO
CALIFORNIA	STATE BOARD OF PHARMACY (916) 445-5014	YES	NO	YES
COLORADO	STATE BOARD OF PHARMACY (303) 894-7753	YES	YES	YES
CONNECTICUT	DEPARTMENT OF CONSUMER PROTECTION (860) 703-6078	YES	NO	NO
DELAWARE	STATE BOARD OF PHARMACY (302) 739-4798	YES	NO	NO
FLORIDA	DEPARTMENT OF HEALTH & REHABILITATIVE SERVICES (850) 487-1257	NO	NO	YES
GEORGIA	STATE BOARD OF PHARMACY (478) 207-1686	YES	NO	YES
HAWAII	BUREAU OF NARCOTICS ENFORCEMENT (808) 594-0150	YES	NO	NO
IDAHO	STATE BOARD OF PHARMACY (208) 334-2356	YES	NO	NO
ILLINOIS	DEPT. OF ALCOHOLISM & SUBSTANCE ABUSE (312) 814-6390	YES	NO	YES
INDIANA	STATE BOARD OF PHARMACY (317) 233-4403	NO	NO	NO
IOWA	STATE BOARD OF PHARMACY (512) 281-5944	YES	NO	NO
KANSAS	STATE BOARD OF PHARMACY (316) 694-9066	NO	NO	NO
KENTUCKY	DRUG CONTROL BRANCH CABINET OF HUMAN RESOURCES (502) 564-7985	YES	NO	NO

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
LOUISIANA	STATE BOARD OF PHARMACY (225) 295-8567	NO	NO	NO
MAINE	STATE BOARD OF PHARMACY (207) 624-8603	YES	NO	NO
MARYLAND	CONTROLLED SUBSTANCE DIVISION OF DRUG CONTROL (410) 764-4755	YES	NO	NO
MASSACHUSETTS	DEPT. OF PUBLIC HEALTH (617) 983-6700 & STATE BOARD OF PHARMACY (617) 727-9953	YES	YES	YES
MICHIGAN	HEALTH & REGULATORY DIVISION (517) 373-1737	YES	NO	NO
MINNESOTA	STATE BOARD OF PHARMACY (612) 617-2201	YES	NO	NO
MISSISSIPPI	STATE BOARD OF PHARMACY (601) 354-6750	YES 48 HRS	NO	NO
MISSOURI	STATE BOARD OF PHARMACY (573) 751-0091	YES	NO	YES
MONTANA	STATE BOARD OF PHARMCY (406) 761-5131	NO	NO	NO
NEBRASKA	DEPARTMENT OF HEALTH (402) 471-2118	NO	NO	NO
NEVADA	STATE BOARD OF PHARAMCY (775) 850-1440	YES	NO	NO
NEW HAMPSHIRE	STATE BOARD OF PHARMACY (603) 271-2350	YES	NO	NO
NEW JERSEY	DEPT. OF DRUG CONTROL (973) 504-6359	YES	NO	YES
NEW MEXICO	STATE BOARD OF PHARMCY (505) 841-9102	YES	NO	YES
NEW YORK	NY BOARD OF HEALTH BUREAU OF CONTROLLED SUBSTANCES (518) 402-0707	YES CALL REQUEST FORM	NO	YES
NORTH CAROLINA	STATE BOARD OF PHARMCY (919) 942-4454	YES	NO	YES
NORTH DAKOTA	STATE BOARD OF PHARMACY (701) 328-9535	YES	NO	NO
OHIO	STATE BOARD OF PHARMACY (614) 466-4143	YES CALL 106	NO	YES

2

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
OKLAHOMA	STATE BOARD OF PHARMACY (405) 521-3815 & BUREAU OF NARCOTICS & DRUG ABUSE SERVICES (405) 521-2885	YES	NO	NO
OREGON	STATE BOARD OF PHARMACY (503) 731-4032	YES	YES	NO
PENNSYLVANIA	STATE BOARD OF PHARMACY (717) 712-2029	YES	NO	YES
RHODE ISLAND	COMPLIANCE AND REGULATORY SECTION (401) 222-2837	YES	NO	NO
SOUTH CAROLINA	DEPT.OF HEALTH BUREAU OF DRUG CONTROLL (803) 935-7815	YES	NO	NO
SOUTH DAKOTA	DIVISION OF REGISTRATION&QUALITY INSPECTIONS (605) 773-4520	YES	YES	NO
TENNESSEE	STATE BOARD OF PHARMACY (615) 741-2718	YES	NO	YES
TEXAS	STATE BOARD OF PHARMACY (512) 305-8000	YES	NO	YES
UTAH	DIVISION OF PROFESSIONAL LICENSING (801) 530-6721	YES	YES	YES
VERMONT	STATE BOARD OF PHARMACY (802) 828-2875	YES	NO	NO
VIRGINIA	STATE BOARD OF PHARMACY (804) 662-9919	NO	NO	NO
WASHINGTON	STATE BOARD OF PHARMACY (360) 236-4825	YES	NO	YES
WEST VIRGINIA	STATE BOARD OF PHARMACY (304) 558-0058	YES	NO	YES
WISCONSIN	WISCONSIN DEPT. OF REGULATIONS & LICENSING (608) 266-2815	YES	NO	YES
WYOMING	STATE BOARD OF PHARMACY (307) 234-0294	YES	NO	NO

3

FOIA Confidential Treatment Requested By Cardinal

CONFIDENTIAL

CAH 022128

CAH_MDL_PRIORPROD_DEA07_01188434

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

Note: Only submit reports to the agency in the state in which your facility is located

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
ALABAMA	STATE BOARD OF PHARMACY (336) 206-5666	YES	YES	NO
ALASKA	STATE BOARD OF PHARMACY (907) 465-2589	YES	NO	NO
ARIZONA	STATE BOARD OF PHARMACY (623) 463-2727	YES	YES	YES
ARKANSAS	STATE BOARD OF PHARMACY (501) 682-0190	YES	NO	NO
CALIFORNIA	STATE BOARD OF PHARMACY (916) 445-5014	YES	NO	YES
COLORADO	STATE BOARD OF PHARMACY (303) 894-7753	YES	YES	YES
CONNECTICUT	DEPARTMENT OF CONSUMER PROTECTION (860) 703-6078	YES	NO	NO
DELAWARE	STATE BOARD OF PHARMACY (302) 739-4798	YES	NO	NO
FLORIDA	DEPARTMENT OF HEALTH & REHABILITATIVE SERVICES (850) 487-1257	NO	NO	YES
GEORGIA	STATE BOARD OF PHARMACY (478) 207-1686	YES	NO	YES
HAWAII	BUREAU OF NARCOTICS ENFORCEMENT (808) 594-0150	YES	NO	NO
IDAHO	STATE BOARD OF PHARMACY (208) 334-2356	YES	NO	NO
ILLINOIS	DEPT. OF ALCOHOLISM & SUBSTANCE ABUSE (312) 814-6390	YES	NO	YES
INDIANA	STATE BOARD OF PHARMACY (317) 233-4403	NO	NO	NO
IOWA	STATE BOARD OF PHARMACY (512) 281-5944	YES	NO	NO
KANSAS	STATE BOARD OF PHARMACY (316) 694-9066	NO	NO	NO
KENTUCKY	DRUG CONTROL BRANCH CABINET OF HUMAN RESOURCES (502) 564-7985	YES	NO	NO

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
LOUISIANA	STATE BOARD OF PHARMACY (225) 295-8567	NO	NO	NO
MAINE	STATE BOARD OF PHARMACY (207) 624-8603	YES	NO	NO
MARYLAND	CONTROLLED SUBSTANCE DIVISION OF DRUG CONTROL (410) 764-4755	YES	NO	NO
MASSACHUSETTS	DEPT. OF PUBLIC HEALTH (617) 983-6700 & STATE BOARD OF PHARMACY (617) 727-9953	YES	YES	YES
MICHIGAN	HEALTH & REGULATORY DIVISION (517) 373-1737	YES	NO	NO
MINNESOTA	STATE BOARD OF PHARMACY (612) 617-2201	YES	NO	NO
MISSISSIPPI	STATE BOARD OF PHARMACY (601) 354-6750	YES 48 HRS	NO	NO
MISSOURI	STATE BOARD OF PHARMACY (573) 751-0091	YES	NO	YES
MONTANA	STATE BOARD OF PHARMCY (406) 761-5131	NO	NO	NO
NEBRASKA	DEPARTMENT OF HEALTH (402) 471-2118.	NO	NO	NO
NEVADA	STATE BOARD OF PHARAMCY (775) 850-1440	YES	NO	NO
NEW HAMPSHIRE	STATE BOARD OF PHARMACY (603) 271-2350	YES	NO	NO
NEW JERSEY	DEPT. OF DRUG CONTROL (973) 504-6359	YES	NO	YES
NEW MEXICO	STATE BOARD OF PHARMCY (505) 841-9102	YES	NO	YES
NEW YORK	NY BOARD OF HEALTH BUREAU OF CONTROLLED SUBSTANCES (518) 402-0707	YES CALL REQUEST FORM	NO	YES
NORTH CAROLINA	STATE BOARD OF PHARMCY (919) 942-4454	YES	NO	YES
NORTH DAKOTA	STATE BOARD OF PHARMACY (701) 328-9535	YES	NO	NO
OHIO	STATE BOARD OF PHARMACY (614) 466-4143	YES CALL 106	NO	YES

2

FB04.01

OMB Approval No. 1117 - 0007

U. S. Department of Justice / Drug Enforcement Administration

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE NO.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below.)*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY DISPOSITION	QUANTITY GMS.	QUANTITY MGS.
1	2	3	4	5	6	7
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
15						
16						

FORM DEA-41 (9-01) Previous edition dated 6-86 is usable. *See instructions on reverse (page 2) of form.*

FOIA Confidential Treatment Requested By Cardinal

CAH 022131

EB 04.00

STATE REQUIREMENTS FOR THE REPORTING OF CONTROLLED SUBSTANCE AND PRESCRIPTION DRUG LOSSES

STATE	REPORTED AGENCY	CONTROLLED SUBSTANCES	PRESCRIPTION DRUGS	CARDINAL FACILITY
OKLAHOMA	STATE BOARD OF PHARMACY (405) 521-3815 & BUREAU OF NARCOTICS & DRUG ABUSE SERVICES (405) 521-2885	YES	NO	N0
OREGON	STATE BOARD OF PHARMACY (503) 731-4032	YES	YES	NO
PENNSYLVANIA	STATE BOARD OF PHARMACY (717) 712-2029	YES	NO	YES
RHODE ISLAND	COMPLIANCE AND REGULATORY SECTION (401) 222-2837	YES	NO	NO
SOUTH CAROLINA	DEPT.OF HEALTH BUREAU OF DRUG CONTROLL (803) 935-7815	YES	NO	NO
SOUTH DAKOTA	DIVISION OF REGISTRATION&QUALITY INSPECTIONS (605) 773-4520	YES	YES	NO
TENNESSEE	STATE BOARD OF PHARMACY (615) 741-2718	YES	NO	YES
TEXAS	STATE BOARD OF PHARMACY (512) 305-8000	YES	NO	YES
UTAH	DIVISION OF PROFESSIONAL LICENSING (801) 530-6721	YES	YES	YES
VERMONT	STATE BOARD OF PHARMACY (802) 828-2875	YES	NO	NO
VIRGINIA	STATE BOARD OF PHARMACY (804) 662-9919	NO	NO	NO
WASHINGTON	STATE BOARD OF PHARMACY (360) 236-4825	YES	NO	YES
WEST VIRGINIA	STATE BOARD OF PHARMACY (304) 558-0058	YES	NO	YES
WISCONSIN	WISCONSIN DEPT. OF REGULATIONS & LICENSING (608) 266-2815	YES	NO	YES
WYOMING	STATE BOARD OF PHARMACY (307) 234-0294	YES	NO	NO

FB04.01

OMB Approval No. 1117 - 0007

U. S. Department of Justice / Drug Enforcement Administration

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE NO.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below.)*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	2	3	4	5	6	7
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
15						
16						

FORM DEA-41 (9-01) Previous edition dated **6-86** is usable. *See instructions on reverse (page 2) of form.*

FOIA Confidential Treatment Requested By Cardinal

CAH 022133

Excessive Purchases
Schedule II

ED04.00

Product	Strength	Dosage Limit Hospital	Dosage Limit Retail
Codeine Sulf	All	800 Tabs	400 tabs
Dextroamphetamine (Dexedrine, Dextrastat)	All	700 Tabs/Spans	800 Tabs/Spans
Desoxyn	All	300 Tabs/Grad	500 Tabs/Grad
Hydromorphone	All	900 Tabs	500 Tabs
Methadone (Dolophine)	All	2000 Tabs	700 Tabs
Meperidine (Demerol, Meprozine, Mepergan Fortis)	All	600 Tabs	400 Tabs
Methlyphenidate (Ritalin)	All	800 Tabs	800 Tabs
Morphine Sulfate (MS Contin, MSIR, Oramorph)	All	600 Tabs	500 Tabs
Oxycodone/Acet (Tylox, Roxilox, Roxicet, Percocet, Endocet)	All	3800 Tabs/Caps	1200 Tabs/Caps
Oxycodone/Asa (Percodan, Endodan, Roxiprin)	All	500 Tabs	500 Tabs
Oxycodone (Oxcontin, Roxicodone)	All	800 Tabs	600 Tabs

Excessive Purchases
Schedule III, IV, V

ED04.00

Product	Strength	Dosage Limit Hospital	Dosage Limit Retail
Acetamenophen w/Cod (Tylenol w/Cod, Phenaphen)	All	1400 Tabs	1300 Tabs
Alprazolam (Xanax)	All	1400 Tabs	2500 Tabs
Butalbital Compound (Florinal w/Cod, Fiortal,	All	500 Tabs/Caps	500 Tabs/Caps
Aspirin w/Cod	All	300 Tabs	400 Tabs
Clorazephate (Klonopin)	All	1000 Tabs	800 Tabs
Clorazephate (Tranxene)	All	700 Tabs	1300 Tabs
Diazepam (Valium)	All	1000 Tabs	2500 Tabs
Dexfenfluramine (Redux)	All	400 Caps	500 Caps
Diphenoxylt/Atropine (Lomotil, Lonox)	All	1600 Tabs	7500 Tabs
Dronabinol (Marinol)	All	300 Tabs	400 Tabs
Fenfluramine HCL (Pondimin)	All	800 Tabs	1700 Tabs
Hydrocodone (Anexsia, Dolaset, Hydrocet, Hycodan, Hyphen, Lorcet, Lortab, Zydone, Vicodin)	All	1200 Tabs/Caps	800 Tabs/Caps
Lorazepam (Ativan)	All	1200 Tabs	2400 Tabs
Meprobamate (Miltown, Equanil)	All	600 Tabs	1400 Tabs
Phentermine (Ionamin, Fastin, Adipex-P)	All	600 Tabs	1100 Tabs
Pentazoline (Talwin, Talacen)	All	700 Tabs	700 Tabs
Propoxyphene (Darvon, Darvocet, Propacet)	All	1100 Tabs	1900 Tabs
Temazepam (Restoril)	All	700 Caps	800 Tabs

FC04.00

CardinalHealth

REGULATORY AGENCY CONTACT FORM

1. _____ _____/_____
   Division Name Date Time

2. **Contact was made with:**
   - ❑ DEA Representative
   - ❑ State Board of Pharmacy Representative
   - ❑ FDA Representative
   - ❑ Other _____ (Please indicate agency)

3. **Contact was made by:**
   - ❑ Telephone
   - ❑ Visit at Division
   - ❑ Visit at Agency

4. **Contact initiated by:**
   - ❑ Division
   - ❑ Agency

5. **NAME, ADDRESS, AND TELEPHONE NUMBER OF REPRESENTATIVE**

   _____
   (Name) (Title)

   _____
   (Address) (Office working out of)

   _____
   (City) (State) (Zip)

6. **PURPOSE OF CONTACT (AUDIT, REQUESTING INFORMATION (include DEA's response), REPORTING SUSPICIOUS ORDERS, EXCESSIVE PURCHASES, ETC.)**

   _____
   _____
   _____
   _____
   _____

7. **IF INFORMATION OR RECORDS WERE PROVIDED, COMPLETE THE FOLLOWING:**
   - Information Sent: _____
   - Delivery Method: _____
   - Sent/Delivered By: _____

8. **FOLLOW-UP REQUIRED?** ❑ Yes ❑ No

9. **NAME OF EMPLOYEE COMPLETING THIS FORM:** _____

_____ _____
(Date) (Signed)

WHITE - Division YELLOW - Corporate Compliance

DUB 1301
Rev. 02/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022136

CONFIDENTIAL

CAH_MDL_PRIORPROD_DEA07_01188442

P-14290 _ 00499

DEA-41 (6/1986) Pg. 2

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content, (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	2	3	4	5	6	7
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _____packages purporting to contain the drugs listed on this inventory and have been: ** (1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.

DATE _____ DESTROYED BY: _____

** *Strike out lines not applicable.*

WITNESSED BY: _____

INSTRUCTIONS

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32mg.), etc.
2. All packages included on a single line should be identical in name, content and controlled substance strength.
3. Prepare this form in quadruplicate. Mail two (2) copies of this form to the Special Agent in Charge, under separate cover. Enclose one additional copy in the shipment with the drugs. Retain one copy for your records. One copy will be returned to you as a receipt. No further receipt will be furnished to you unless specifically requested. Any further inquiries concerning these drugs should be addressed to the DEA District Office which serves your area.
4. There is no provision for payment for drugs surrendered. This is merely a service rendered to registrants enabling them to clear their stocks and records of unwanted items.
5. Drugs should be shipped tape-sealed via prepaid express or certified mail (return receipt requested) to Special Agent in Charge, Drug Enforcement Administration, of the DEA District Office which serves your area.

PRIVACY ACT INFORMATION

AUTHORITY: Section 307 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: To document the surrender of controlled substances which have been forwarded by registrants to DEA for disposal.
ROUTINE USES: This form is required by Federal Regulations for the surrender of unwanted Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project no. 1117-0007, Washington, D.C. 20503.

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO: DEA05.00

ISSUE DATE: 6-15-2006

TITLE: Methamphetamine Control Act

PAGE: 1 of 4

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA05.00**
TITLE: Methamphetamine Control Act	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements pertaining to the Methampehtamine Control Act ("MCA")

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1. Each facility that is not a DEA controlled substance registrant, but distributes ephedrine, pseudoephedrine or phenylpropanolamine products covered under the Methamphetamine Control Act ("MCA"), must obtain a DEA Chemical Registration.

2. Each facility must maintain one of the following for each customer who purchases products covered under the MCA in packages containing more than 60 dosage units:

   a.) Photocopy of a valid and current DEA Certificate of Registration (**Exhibit EA05.00**).

   b.) Photocopy of a valid and current DEA Chemical Registration (**Exhibit EB05.00**).

3. Each facility must maintain readily retrievable records for each MCA product transaction which contain:

   a.) The name and address of each party to the transaction.

   b.) The date of the transaction.

   c.) The name, quantity, and form of packaging of the MCA product.

   d.) The method of transfer.

   e.) The type of identification used by the purchaser.

4. Each facility shall report to their local DEA office:

   a.) Unusual MCA transactions or suspicious circumstances (i.e. extraordinary quantity, uncommon method of payment or delivery).

   b.) Unusual or excessive loss of MCA products.

   c.) Proposed transaction with a person DEA has requested in writing that you monitor (report before completing sale).

5. The procedure for reporting MCA transactions or losses shall be as follows:

   a.) Reports shall be made orally, whenever possible, to the local DEA office at the earliest opportunity and as much in advance of the sale as possible; or

   b.) A written report (**Form FA05.00**), containing the following information, must be filed within fifteen (15) days of becoming aware of the transactions or losses:

      i.) Written reports must contain the same information as required records.

      ii.) The telephone number of the other party (if possible).

      iii.) A description of the circumstances leading you to make the report.

6. The facility must generate and review, on a monthly basis, the MCA Dosage Limit Report (**Exhibits EC05.00 and ED05.00**).

   a.) A copy of the report shall be submitted to the local DEA office via registered or certified mail, return receipt requested.

7. **The facility must conduct inventories of these products according to "Inventory Guidelines for Products Covered Under the Methamphetamine Control Act ("MCA")" (Exhibit EE05.00).**

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO: DEA05.00

ISSUE DATE:

TITLE: Methamphetamine Control Act

8. The facility shall maintain a file consisting of:

   a.) MCA reports submitted to DEA.

   b.) Monthly MCA Dosage Limit Report.

EA05.00

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041

[redacted] MA 01960 - 0000

DEA REGISTRATION NUMBER: RD0108200
THIS REGISTRATION EXPIRES: [redacted]
FEE PAID: PAID
SCHEDULES: 2, 3,3N,4,5
BUSINESS ACTIVITY: [redacted]
ISSUE DATE: 04-25-2006

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041
PEABODY MA 01960-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0108200	05-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2, 3,3N,4,5	DISTRIBUTOR	04-25-2006

CARDINAL HEALTH
11 CENTENNIAL DRIVE
P O BOX 6041
PEABODY MA 01960-0000

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (1/98)

FOIA Confidential Treatment Requested By Cardinal

CAH 022143

FA05.00

CardinalHealth

MCA TRANSACTION REPORT

Excessive Purchase ☐ **Loss or Theft** ☐ **DEA Request** ☐

Supplier:

Name: _____
Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Telephone: _____

Purchaser:

Name: _____
Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Telephone: _____
Identification: _____

Shipping Address (If different than purchaser address):

Street: _____
City: _____
State: _____
Zip Code: _____
Date of Shipment: _____

Product Description: _____

Quantity and Form of Packaging: _____

If Loss or Disappearance:

Date of Loss: _____
Type of Loss: _____

Description of Circumstances: _____

FOIA Confidential Treatment Requested By Cardinal

CAH 022144

EC05.00

RUN DATE: 7/14/99 7:54:53 CARDINAL - SYRACUSE PAGE: 1

MCA Dosage Limit Report (DETAIL)

MONTH : JUN 1999 FOR HOSPITAL/MANAGED CARE MCAJ007P1

Invoice	Invoice Item	NDC	Item	Form	Qty	Item	Total
Date	Number Number	Number	Description		Sold	Dosage	Dosage

Customer: 349902 WILKES-BARRE GEN HOSP RT140- N. RIVER & AUBURN ST. WILKES BARRE PA 18764-0000 DEA Lic: AW2452655

INGREDIENT: 002 PSEUDOEPHEDRINE

6/02/1999	8366378	1098649	45040542	TYLENOL SINUS MAX STRN 24	TB		8	24	192
6/05/1999	8377413	1098649	45040542	TYLENOL SINUS MAX STRN 24	TB		48	24	1,152
6/10/1999	8389560	1098649	45040542	TYLENOL SINUS MAX STRN 24	TB		60	24	1,440
6/19/1999	8416539	1286640	54474335	PSEUDOEPHED HCL 30MG 100	ROX	TB	100	100	10,000
6/16/1999	8405162	1321785	536102135	ALLERFRIM 24 OTC BLST	WAT	TB	12	24	288
6/19/1999	8416539	1321785	536102135	ALLERFRIM 24 OTC BLST	WAT	TB	12	24	288
								CUSTOMER TOTAL:	13,360
								INGREDIENT LIMIT:	10,174

Customer: 620188 GEO MOTCHAN DETENTION CTR 15-15 HAZEN STREET EAST ELMHURST NY 11370-0000 DEA Lic: AM6222525

INGREDIENT: 003 PHENYLPROPANOLMINE

6/03/1999	8369699	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/03/1999	8369701	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		4	100	400
6/04/1999	8373353	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/07/1999	8377935	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/07/1999	8377942	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/07/1999	8377946	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		2	100	200
6/07/1999	8378427	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/10/1999	8389164	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/10/1999	8389165	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		6	100	600
6/11/1999	8392866	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/14/1999	8397468	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/14/1999	8397471	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/17/1999	8409076	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/18/1999	8412502	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/18/1999	8412503	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/18/1999	8412504	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		4	100	400
6/21/1999	8417127	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/21/1999	8417137	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		1	100	100
6/21/1999	8417143	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		4	100	400
6/24/1999	8429811	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/24/1999	8429813	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		4	100	400
6/25/1999	8433446	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		10	100	1,000
6/25/1999	8433447	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/28/1999	8437992	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		1	100	100
6/28/1999	8437996	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		5	100	500
6/28/1999	8437998	1361005	31227764	DIMETAPP EXT 100 UD 2277-64	TB		4	100	400
								CUSTOMER TOTAL:	16,500
								INGREDIENT LIMIT:	4,121

*** END OF REPORT ***

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control
Suspicious Orders Task Force

EXHIBIT II

SUSPICIOUS ORDER REPORTING SYSTEM OF 1998
For Use in automated tracking systems

The Current Calculation Being Used
for List I Chemicals and Schedule II - V Controlled Substances

Terms & Definitions

This formula is used to calculate the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero).

3) Divide total quantity purchased by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

   Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III N-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II - V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycles times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

INVENTORY GUIDELINES FOR PRODUCTS COVERED UNDER THE METHAMPHETAMINE CONTROL ACT ("MCA")

DEA has specific regulations pertaining to recordkeeping and reporting requirements for listed chemicals covered under the MCA. (Refer to 21 CFR 1310 and the Corporate DEA Compliance Manual, Tab 6).

Additionally, most states have passed, or are in the process of passing, regulations pertaining to ephedrine ("EPH"), pseudoephedrine and ("PSE") products.

Effective immediately, the following guidelines are to be followed for EPH and PSE products. **The guidelines pertain only to single-entity, solid dosage forms.**

- Randomly select 12 solid dosage forms, from your last MCA report, of EPH and PSE products. The 12 products should be a combination of both products (i.e. 2 EPH, 10 PSE).
- Perform a physical count of each selected product. Include live, morgue and brokerage inventories in the physical count. **EPH and PSE counts should be performed during your regular monthly controlled drug inventory.**
- Any significant or unusual shortage must be thoroughly researched. The following factors should be considered when determining "significant" or "unusual" discrepancies:
    - The variance equals a full shelf pack or case quantity.
    - The variance is greater than 200 dosage units of the same product.
    - Repeated shortages of the same product, same vendor or same product, different vendors.
- Adjustments for all **unresolved shortages** of these products must be documented on the controlled substance monthly adjustment form, which you are now required to submit to your QRA Manager.
- Notify your local DEA office immediately of all significant or unusual unresolved inventory shortages of EPH and PSE products. The initial notification should be made orally and a written report must be filed within 15 days. (Refer to MCA Transaction Report (Form 8) in the Corporate DEA Compliance Manual.)
- If your domicile State requires notification of significant or unusual shortages for these items, follow their instructions.

REMINDER: You must also notify DEA of any unusual or excessive purchases, by your customers, of these products. Please review the information in the Corporate DEA Compliance Manual, Tab 6.

October 17, 2005

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA06.00

TITLE: Structural Security for Vault and Cage

ISSUE DATE: 6-5-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.00**
TITLE: Structural Security for Vault and Cage	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for the construction of the controlled substance vault and cage.

SCOPE: Pharmaceutical Distribution Facilities

POLICY:

1.) Schedule II controlled substances shall be stored in a vault, the physical structure of which meets the following specifications or equivalent:

a.) A grandfathered vault, one which was constructed before or under construction on September 1, 1971, must:

i.) Be of substantial construction.

ii.) Have a steel door.

iii.) Have a combination or key lock.

b.) A vault constructed after September 1, 1971, must:

i.) Have walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry.

ii.) Be reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceiling.

c.) The door and frame unit of the vault (GSA approved, Class V) must conform to the following specifications or equivalent:

i.) 30 man minutes against surreptitious entry.

ii.) 10 man minutes against forced entry.

iii.) 20 man hours against lock manipulation.

iv.) 20 man hours against radiological techniques.

Reference: DEA Correspondence November 29, 1993 for a change in the specifications for the GSA Class V vault door.

NOTE: DEA will approve, on a case by case basis, UL listed Class M modular vaults.

d.) If the vault is to remain open for frequent access, it must be equipped with a 'day gate', which must be self-closing and self-locking, or the equivalent.

2.) Schedule III, IIIN, IV and V controlled substances shall be stored in a cage that meets the following specifications:

a.) Walls must be constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

i.) At least one inch in diameter.

ii.) Set in concrete or installed with lag bolts that are pinned or brazed.

iii.) Placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches.

b.) Mesh construction with openings of not more than two and one half inches across the square.

c.) A ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building.

i.) A lighter gauge mesh may be used for the ceilings of large enclosed areas if the walls are at least 14 feet in height.

d.) Be equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange.

i.) Door must be self-closing, self-locking and constructed of substantial material commensurate with the type of building construction.

ii.) A door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door.

e.) Door must be sliding or hinged.

i.) Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal.

ii.) The track holding sliding 10-gauge steel gates in place must be adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track.

f.) Locking devices for doors shall be either of the multiple-position combination or key lock type.

i.) In the case of key locks, the division must have key control that limits access to a limited number of employees.

ii.) In the case of combination locks, the combination shall be limited to a minimum number of employees and shall be changed upon termination of employment of an employee having knowledge of the combination.

g.) Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

h.) Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in the secure storage area.

i.) Permission must be obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated.

ii.) Security effectiveness for Schedule III through V controlled substance storage must not be diminished.

iii.) Authorization must be posted, in plain sight, in the secured area.

iv.) A copy of the authorization letter must be maintained on file.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.01**
TITLE: Alarm Systems for Controlled Drug Areas	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 4
RESPONSIBILITIES:	
APPROVALS:	

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.01**
TITLE: Alarm Systems for Controlled Drug Areas	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for alarm systems in the narcotic vault and controlled drug cage areas.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The narcotic vault must be on a separate, stand alone alarm system with the following minimum security requirements:

a.) The walls or perimeter of the vault shall be equipped with an alarm that includes standby power sources which, upon unauthorized entry, transmits a signal over a supervised alarm transmission circuit directly to one of the following:

i.) A central station protection agency.

ii.) A local or state police agency that has legal duty to respond.

iii.) A 24-hour control station operated by the registrant.

iv.) To such other source of protection as approved by DEA.

b.) The door of the vault shall be equipped with contact switches.

c.) The vault shall be equipped with one of the following:

i.) Complete electrical lacing of the walls, floor and ceiling.

ii.) Sensitive ultrasonic, microwave or passive infrared equipment.

iii.) A sensitive sound accumulator system.

iv.) Such other device designed to detect illegal entry as approved by DEA.

d.) Additional motion detectors shall be positioned directly outside and along the approach to the vault in order to detect anyone approaching the vault when the alarm is set.

e.) When necessary, due to local conditions or other problems, hold-up alarms shall be placed at strategic points of entry to the perimeter area of the vault.

2.) The controlled cage must be equipped with the following alarm protection:

a.) An alarm system which, upon unauthorized entry, shall transmit a signal directly to one of the following:

i.) A central station protection agency.

ii.) A local or state police agency that has legal duty to respond.

iii.) A 24-hour control station operated by the registrant.

iv.) To such other source of protection approved by DEA.

3.) The cage and vault alarm systems must be tested annually by the alarm contractors. The inspection shall include:

a.) A test and adjustment of the entire alarm system.

b.) Replacement of any components, sensors or wiring that are defective.

c.) A written confirmation confirming the results of the inspection and certifying that the system continues to meet the contractual obligations between the company and the alarm contractor and any applicable UL certification standards.

4.) The facility must conduct a monthly walk test of the alarm equipment surrounding the vault and cage areas which includes:

a. The vault door alarm contact switch.

b. Motion sensing or capacitance devices used in conjunction with vault and cage protection.

c. Immediate correction to any alarm equipment failures.

5.) The facility shall document the test on a Monthly Alarm Walk Test Report (**Form FA06.01**) which shall be filed and distributed accordingly.

6.) Records documenting the annual alarm test by the alarm contractors and the monthly walk tests conducted by the facility shall be retained on file for a 36-month period for review by any DEA agent.

CardinalHealth

FA06.01

Monthly alarm walk-test

Division _____ for the month of _____

Alarm company's name _____

Number of false alarms in the past month _____

Last false alarm _____

Cause of false alarm _____

Corrective action taken _____

_____

Instructions

Please check the following alarm equipment and indicate that it is functioning properly by placing a mark in the space provided.

_____ Alarm call-up list is up-to-date

_____ Ambush/Duress code on control panel is functioning

_____ Sensitivity of all motion detectors is set correctly

_____ Boxes and shelves are NOT blocking motion detectors

_____ Photoelectric beams have a clean line of sight

_____ Door contacts and audible alarms are functioning properly

_____ Vault alarm system is functioning properly (scheduled openings & closings)

_____ All closed circuit television cameras are working properly

_____ All closed circuit television camera monitors are working properly

_____ All electronically controlled doors are functioning properly

_____ All robbery buttons are functioning properly (battery back-ups on hand-held buttons are fresh)

_____ All intercoms are working properly

_____ _____

Signature of employee completing form Date

This form is to be completed at the end of each month. Copy must be sent to the Corporate Security department by the 15th of the following month.

White - Division Yellow - Corporate Compliance

DUB 1306
Rev 10/04

FOIA Confidential Treatment Requested By Cardinal

CAH 022158

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.02**
TITLE: Access Control	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 4
RESPONSIBILITIES:	
APPROVALS: Approved by: _____ Date: 6-5-06 Stephen J. Reardon Vice President, Quality & Regulatory Affairs	

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.02**
TITLE: Access Control	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements to limit access to warehouse and controlled substance storage areas.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each facility shall limit access to the general warehouse.

a.) Warehouse access shall be limited to employees who have a full-time work assignment that requires their presence in the warehouse.

b.) The facility shall maintain a list of employees authorized to have warehouse access.

c.) Access shall be controlled by a Card Entry Access Control System or other system designed to restrict entry.

d.) The following groups must be excluded from warehouse access without a full-time escort:

i.) All visitors.

ii.) Vendor sales representatives.

iii.) Cardinal Health sales representatives.

iv.) Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs.

v.) Office employees except those whose duties require their presence in the warehouse.

e.) Limited access signs must be posted on all warehouse entrances.

f.) Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

g.) Employees of Cardinal Health Pharmaceutical Distribution who require temporary access to the warehouse shall be issued "temporary passes" controlled by the facility manager or designee.

2.) Each facility shall limit access to the Controlled Substance areas.

a.) The controlled substances storage areas shall be accessible only to a minimum number of specifically authorized employees.

b.) Adequate observation shall be provided when it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substance storage areas.

i.) Observation shall be provided by an employee specially authorized in writing.

c.) The facility shall maintain an **Access and Surveillance List (Form FA06.02)** of those employees with access to the cage and vault.

d.) Only individuals on the **Access and Surveillance List** shall be assigned a key or knowledge of a combination.

e.) The authorized access list must be posted on the cage and vault doors.

f.) A **"Restricted Area"** sign **(Exhibit EA06.02)** must be posted on the cage and vault doors.

g.) Temporary employees must never be allowed access to the cage or vault.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.02**
TITLE: Access Control	**ISSUE DATE:**
	PAGE: 4 of 4

3.) Each facility shall limit access to the computer system.

a.) The computer system must include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access.

b.) Employees must keep passwords confidential.

c.) Passwords must be changed periodically to prevent access by others.

d.) Access must be limited for the following files:

i.) Inventory adjustments

ii.) Customer licensing information

CARDINAL HEALTH FA06.02

_____ Division

ACCESS AND SURVEILLANCE LIST

The following personnel are permitted unsupervised access to the cage and vault area:

If any person other than those listed above requires job-related temporary access to this area, they must be escorted by a person with approved cage and vault access.

_____

Signature

_____

Title

_____

Division

_____

Date

FOIA Confidential Treatment Requested By Cardinal

CAH 022163

EA06.02

RESTRICTED AREA

AUTHORIZED PERSONNEL ONLY

UNAUTHORIZED PERSONNEL ENTERING THIS AREA WILL BE SUBJECT TO SEVERE DISCIPLINARY ACTION INCLUDING DISCHARGE

THIS ANNOUNCEMENT MADE NECESSARY BY INCREASED STATE AND FEDERAL RESTRICTIONS PERTAINING TO THE HANDLING AND CONTROL OF DANGEROUS DRUGS.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA06.03

TITLE: Lock and Key Control for Controlled Substance Areas

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality& Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.03**
TITLE: Lock and Key Control for Controlled Substance Areas	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for lock and key control for the narcotic vault and controlled cage areas.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility shall maintain a lock and key control system for:

   a.) All entrance gates to the controlled cage.

   b.) The narcotic vault day-gate.

   c.) The combination lock to the narcotic vault.

2.) The facility shall change all locks on the controlled cage and vault and the combination to the vault as follows:

   a.) At least annually.

   b.) When an employee having access to the keys to these areas and/or the combination to the vault leaves the company's employ or is transferred to a new location.

3.) A Key Log (**Form FA06.03**) must be maintained and a Key Receipt (**Form FB06.03**) must be issued for each key distributed at the facility.

4.) Copies of key receipts shall be distributed as follows:

   a.) One copy to the employee.

   b.) One copy to the facility manager.

   c.) One copy placed in the employee's personnel file.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.03**
TITLE: Lock and Key Control for Controlled Substance Areas	**ISSUE DATE:** **PAGE:** 3 of 3

5.) When an employee is entrusted with a passcard, the number must also be recorded on a key receipt form.

6.) Keys to the vault day gate and controlled cage areas and the combination to the vault must be kept:

a.) On the person of the employee entrusted in their care; or

b.) In a locked desk drawer or small locked cabinet.

7.) A spare key to the vault must be secured inside the vault in an inconspicuous location.

8.) Spare keys to the controlled cage and vault day gate and the combination to the vault must be kept in a secured area.

FA06.03

CARDINAL HEALTH

_____ Division

KEY LOG

The following personnel have been issued keys to this facility:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Signature

_____

Title

_____

Division

_____

Date

FB06.03

Cardinal Health

Key Receipt

Employee Name: _____ Date: _____

Department: _____ Key Number: _____

I understand that I am responsible for the proper use of the key and will take all reasonable precautions to prevent any misuse. I will immediately notify the Cardinal Health Corporate Security Department in the event of theft or any other loss of the key. I will not have any copies of the key made and will turn in the key to the Cardinal Health Corporate Security Department when my employment terminates for whatever reason.

Employee Signature: _____

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA06.04

TITLE: Procedural Security

ISSUE DATE: 6-15-2006

PAGE: 1 of 8

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA06.04**
TITLE: Procedural Security	**ISSUE DATE:** **PAGE:** 2 of 8

PURPOSE: To comply with DEA and Cardinal Health, Inc. procedural requirements for the handling of controlled substances.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Receiving

a.) Upon receipt, controlled substance items shall be physically checked by a receiving clerk.

b.) The quantity and description of the product shall be checked against the packing list provided by the vendor.

c.) The vendor address and DEA registration number on the packing list and quantity and description of the product shall be checked against the controlled substance purchase order.

d.) The paperwork shall be signed and dated by the receiving clerk.

e.) Variations in the vendor information and in quantities or visible damage to cartons shall be reported to the supervisor prior to the departure of the carrier's representative from the area.

i.) The carrier's representative must sign a statement, written on the receiving report, describing the shortage or damage.

ii.) The receiving procedure must be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

iii.) Vendor information shall be updated as necessary.

f.) If a noted discrepancy cannot be reconciled:

i.) The manufacturer shall be contacted immediately by telephone.

ii.) Confirmation of the shortage or damage shall be verified in writing on the appropriate form.

g.) The loss of controlled substances must be promptly reported to the local DEA office per SOP **DEA04.00.**

i.) The supplier must report in-transit losses of controlled substances by the common or contract carrier upon discovery of such theft or loss.

ii.) Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

h.) Upon verification of the order received, the controlled substances and corresponding paperwork shall be placed in a rolling locked cage and moved to the vault or to the controlled substance cage.

i.) Controlled substances must never be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

2.) Stocking

a.) All products and quantities shall be verified against paperwork.

b.) Each purchase order shall be signed and dated.

c.) Discrepancies shall immediately be brought to the attention of the supervisor.

d.) The original paperwork shall be forwarded to the appropriate department for data entry.

e.) A copy of the paperwork shall be retained in the controlled substance area.

f.) Schedule II items:

i.) Product shall be verified against Copy 3 (blue) of the DEA order form.

ii.) The date received and quantity received columns of the order form shall be completed.

iii.) The Narcotic Order Blank Log shall be updated.

3.) Order Filling, Schedule III, IV, V

a.) The order filler shall pick the items and quantities as requested on the picking document.

b.) As items are picked, each line of the picking ticket shall be initialed.

c.) The completed order and paperwork shall be staged pending verification.

4.) Order Filling, Schedule II

a.) The order form, DEA Form 222, shall be reviewed for accuracy.

b.) The DEA order form shall be matched to the picking document to ensure that all items agree.

c.) The items and quantities shall be picked as requested on the picking document.

d.) The picking document shall be initialed as each item is picked.

e.) The completed order and paperwork shall be staged pending verification.

f.) The following fields on the order form must be filled in:

i.) Packages shipped

ii.) Date shipped

iii.) Supplier DEA Registration Number

5.) Quality Control

a.) All controlled substance orders must be double checked for accuracy.

i.) The quality control clerk shall match the items against the picking document and initial the paperwork.

b.) The merchandise and copy of the packing slip shall be put in a shipping container and sealed, preferably a heat-sealed poly bag.

c.) One copy of the pick document shall be retained at the facility.

d.) The outside of the package shall be labeled with the name of the customer.

e.) The package must have no marks identifying the contents as controlled substances.

f.) The order shall be staged within the controlled substance area until shipped.

6.) Shipping

a.) Controlled substance orders shall be manifested in the cage or vault.

b.) Controlled substance orders shall not be left unattended in the shipping department.

c.) Controlled substance orders shall be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

7.) Delivery

a.) The driver must obtain a customer signature for any orders delivered.

b.) The proof of delivery (manifest) shall be returned to the carrier or division.

c.) The proof of delivery (manifest) shall be retained per division policy.

8.) Returns From Customers

a.) All returns of controlled substances must be accompanied by a return authorization.

b.) The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers.

c.) Upon receipt at the facility, the returns shall:

i.) Be transferred to the controlled substance area.

ii.) Be processed daily.

iii.) Have the actual date of receipt noted.

d.) Return of Schedule II drugs shall be discouraged.

e.) Schedule II drug returns shall be handled by issuing an order form, DEA Form 222, to the customer.

f.) Partial returns of controlled substances shall be prohibited.

9.) Returns to Vendors

a.) Controlled substances returned to the vendor must be accompanied by:

i.) A return authorization from the vendor.
ii.) A debit memo from the division.

b.) A debit memo shall be created to remove the product from inventory.

c.) The debit memo must reflect the address and DEA registration number of the "ship to" location as indicated on the return authorization.

d.) Proof of delivery shall be filed at the division with a copy of the debit memo.

10.) Physical Verification of Controlled Substances

a.) When conducting an inventory, the following steps shall be taken:

i.) Do not allow any product into or out of the area during the count or recount.

ii.) Counts should be conducted from count sheet with the on hand quantities suppressed.

iii.) Compare the inventory results with the current on-hand balance of each item.

iv.) Recount any out-of-balance item.

v.) Run audit report for any out-of-balance item. The **Selected Item Audit Report (Exhibit EA06.04)** gives all movement including purchases, returns, sales and inventory adjustments for a requested item during a specified time frame.

vi.) Research the error, checking for orders picked but not invoiced, mispicks, etc.

vii.) Make appropriate adjustments as errors causing variances are detected.

b.) The distribution center manager shall sign off on the count sheet that he/she has reviewed all exceptions and that variances have been explained.

c.) File DEA Form 106, on a timely basis per SOP **DEA04.00**, for any item that cannot be resolved.

11.) Inventory Adjustments

a.) Inventory adjustments for controlled substances shall only be made after through research.

b.) Documentation shall be kept on file to support any adjustments.

12.) Breakage

a.) Breakage occurring in the cage or vault or during delivery shall be documented.

b.) A breakage report shall be maintained to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

CardinalHealth

FA07.02

REGULATORY AGENCY CONTACT FORM

1. _____ _____/_____
Division Name Date Time

2. **Contact was made with:**
- ❑ DEA Representative
- ❑ State Board of Pharmacy Representative
- ❑ FDA Representative
- ❑ Other _____ (Please indicate agency)

3. **Contact was made by:**
- ❑ Telephone
- ❑ Visit at Division
- ❑ Visit at Agency

4. **Contact initiated by:**
- ❑ Division
- ❑ Agency

5. **NAME, ADDRESS, AND TELEPHONE NUMBER OF REPRESENTATIVE**

_____
(Name) (Title)

_____
(Address) (Office working out of)

_____
(City) (State) (Zip)

6. **PURPOSE OF CONTACT (AUDIT, REQUESTING INFORMATION (include DEA's response), REPORTING SUSPICIOUS ORDERS, EXCESSIVE PURCHASES, ETC.)**

_____
_____
_____
_____
_____

7. **IF INFORMATION OR RECORDS WERE PROVIDED, COMPLETE THE FOLLOWING:**

Information Sent: _____
Delivery Method: _____
Sent/Delivered By: _____

8. **FOLLOW-UP REQUIRED?** ❑ Yes ❑ No

9. **NAME OF EMPLOYEE COMPLETING THIS FORM:** _____

_____ _____
(Date) (Signed)

WHITE - Division YELLOW - Corporate Compliance

DUB 1301
Rev. 02/03

FOIA Confidential Treatment Requested By Cardinal

CAH 022179

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:
DEA07.00

TITLE: Controlled Substance Shipping and Delivery

ISSUE DATE: 6-5-2006

PAGE: 1 of 4

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.00**
TITLE: Controlled Substance Shipping and Delivery	**ISSUE DATE:**
	PAGE: 2 of 4

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for shipment and delivery of controlled substances and to adequately secure and guard against internal and in-transit losses.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) All controlled substance orders must be packed in sealed packages or containers.

   a.) Schedule I and II products shall be packaged separately from Schedule III through V products.

   b.) Packages or containers must not be marked in any way indicating contents are controlled substances.

2.) Schedule I or II controlled substances orders must be retained in the vault until the driver assigned to such delivery is ready to depart the premises.

   a.) The order shall be delivered by the vault supervisor to the driver.

   b.) The driver shall:

      i.) Sign the log.

      ii.) Circle the order number of the merchandise on the manifest.

      iii.) Load the packages or containers into the delivery vehicle.

3.) Schedule III through V controlled substance orders must be retained in the controlled substance cage or staged in a defined controlled substance shipping area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system.

a.) The driver assigned to the specific orders shall:

i.) Sign the log.

ii.) Circle the order number of the merchandise on the manifest.

iii.) Load the packages or containers into the delivery vehicle.

4. Controlled substances orders shall not be left on the shipping dock during times when the facility is closed.

5. Unshipped controlled substance orders shall be returned to the vault or the controlled substance cage.

6. The shipping department supervisor must make a thorough search for controlled substance orders remaining in the shipping area prior to his/her departure from the area at the end of the business day.

7. Controlled substance orders shall only be delivered to:

a.) Persons properly registered with DEA to possess controlled substances.

b.) The registered location listed on the customer's current and valid DEA Registration Certificate.

8. Company delivery vehicles used for delivery and pick-up of controlled substances must be equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

a.) Company delivery drivers must be screened in accordance with 21 CFR 1301.90 and review and sign Delivery Vehicle Security Rules (**Form FA07.00**). Upon delivering the controlled substance order to the customer, the driver shall:

i.) Obtain a customer signature on one copy of the delivery order.

ii.) Attach the signed delivery order to the manifest as proof of delivery.

9. The facility shall select common or contract carriers that provide adequate security to guard against in-transit losses. The facility must provide contract carriers Delivery Vehicle Security Rules for distribution to their drivers. Contract drivers shall review and sign security rules.

10. When distributing controlled substances through agents, the facility shall provide and require adequate security to guard against theft and diversion while the substances are stored or handled by the agent or agents.

CardinalHealth

FA07.00

DELIVERY VEHICLE SECURITY

The following rules are intended to promote safety and security for drivers and their delivery vehicles. They are to be complied with at all times.

1. Keep all merchandise in the rear of the truck. Leave nothing in the cab.

2. Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.

3. Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

4. Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.

5. If you break down, stay with your truck. Leave only to call for assistance.

6. Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.

7. In the event of a robbery:
   a. Offer no resistance.
   b. Stay calm.
   c. Be observant.

Driver Signature: _____

Witness Signature: _____

Date: _____

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.01**
TITLE: Dedicated Depots/Line Haul Shipments	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 3
RESPONSIBILITIES:	
APPROVALS: Approved by: _____ Date: 6-5-06 Stephen J. Reardon Vice President, Quality & Regulatory Affairs	

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.01**
TITLE: Dedicated Depots/Line Haul Shipments	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements to prevent theft and/or diversion during the line haul run from the distribution center to the depot.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The contents of each line haul vehicle must be checked and driver signatures obtained at each pickup and delivery.

2.) Dedicated line haul vehicles shall be secured by a Cardinal Health Pharmaceutical Distribution employee via a numbered seal that must be cut off or broken upon arrival at the depot.

a.) Seal construction shall be as follows:

i.) The seal must be strong enough to prevent accidental breakage during normal use.

ii.) The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

iii.) The seal shall provide readily visible evidence of tampering and prevent reconstruction after the seal is closed.

iv.) The seal shall be individually identifiable by embossing serial numbers and owner identification on each seal.

3.) Seal numbers must be entered or written on transportation documents (i.e bills of lading, manifests).

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.01**
TITLE: Dedicated Depots/Line Haul Shipments	**ISSUE DATE:** **PAGE:** 3 of 3

4.) Trailers must be sealed immediately after loading is complete.

a.) Roll-up type doors must be sealed at the loading dock.

b.) Swing out doors must be sealed immediately after the vehicle is far enough away from the dock to close door.

5.) Seal examination and verification must be performed at each stop (docks and transfer points).

6.) Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation.

7.) Broken seals shall be retained until it is determined whether there are any discrepancies.

a.) If there are no discrepancies, the seal shall be destroyed.

b.) If a discrepancy is found, the seal shall be retained, pending investigation.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.02**
TITLE: Freight Forwarding Facility Operated by a DEA Registrant	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 3
RESPONSIBILITIES:	
APPROVALS:	

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.02**
TITLE: Freight Forwarding Facility Operated by a DEA Registrant	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for freight forwarding facilities operated by a DEA Registrant.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Prior to initiating operations, the distribution center must submit a written notice of intent to operate the facility by registered mail, return receipt request, to the DEA field offices in both the area in which the freight forwarding facility is located and the area of the registered location. The notice must contain the following:

a.) Name, address and DEA number of the registered location.

b.) Address of the freight forwarding facility.

c.) Hours of operation.

d.) Name of person in charge.

e.) Security and record keeping procedures.

f.) Whether or not returns will be processed through the facility.

g.) Applicable state requirements (contact appropriate agencies and document on Regulatory Agency Contact Form (**Form FA07.02**).

h.) Request for central record keeping authorization, if applicable, per SOP DEA 02.00.

2.) Controlled substances temporarily stored at a freight forwarding facility must be held:

a.) In a controlled substance cage; or

b.) In a segregated area under constant supervision.

3.) Access to the controlled substances must be limited.

4.) Controlled substances must not be held in the freight forwarding facility for more than 24 hours.

5.) Controlled substances must be packaged in sealed, unmarked shipping containers.

6.) Records documenting the distribution or return of controlled substances through the freight forwarding facility must contain the following:

a.) Date and time of transfer.

b.) Number of containers transferred.

c.) Authorized signature for each transfer.

7.) Records must be maintained at the freight forwarding facility unless central record keeping permission has been obtained from the local DEA office.

8.) Control substances returned through the freight forwarding facility must be:

a.) Pre-authorized.

b.) Delivered by the customer directly to an employee or agent of the registrant.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA07.03

TITLE: Will Call Orders and U.S. Postal Shipments of Controlled Substances

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.03**
TITLE: Will Call Orders and U.S. Postal Shipments of Controlled Substances	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements regarding will call orders and U.S. postal shipments of controlled substances.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Will Call Orders

a.) Will call orders must be verified by a telephone call to the person in charge of the licensed premises for whom the order is intended. The following information shall be obtained:

i.) The name of the person picking up the order; and

ii.) The item or items included in the order.

b.) When the individual arrives to pick up the order, the shipping supervisor or designee shall verify the name of the person picking up the order by requesting to see a driver's license.

c.) The person picking up the order must sign the Will Call Log (**Form FA07.03**).

d.) The shipping supervisor or designee must complete the Will Call Log.

e.) The driver's license number and the name of the person picking up the order must be recorded on:

i.) The packing slip.

ii.) The Will Call Log.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.03**
TITLE: Will Call Orders and U.S. Postal Shipments of Controlled Substances	**ISSUE DATE:** **PAGE:** 3 of 3

2.) U.S. Postal Shipments

a.) Controlled substance orders shipped through the U.S. postal service must be:

i.) Shipped by registered mail, return receipt requested.

ii.) Sent from one DEA registrant to another DEA registrant.

iii.) Packaged in plain outer containers, giving no indication of the contents.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA07.04

ISSUE DATE: 6-5-2006

TITLE: Delivery Driver Security Rules

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA07.04**
TITLE: Delivery Driver Security Rules	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for maintaining security on shipments.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Delivery drivers must adhere to the following security rules:

a.) Test all vehicle locks each day and immediately report defects to a supervisor.

b.) Keep all merchandise in the rear of the truck. Leave nothing in the cab.

c.) Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.

d.) Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

e.) Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.

f.) If you break down, stay with your truck. Leave only to call for assistance.

g.) Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.

h.) In the event of a robbery:

i.) Offer no resistance.

ii.) Stay calm.

iii.) Be observant

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO: DEA07.04

ISSUE DATE:

TITLE: Delivery Driver Security Rules

2. Delivery driver security rules (**Form FA07.04**) must be distributed to all drivers and a signature obtained to document receipt.

WILL CALL LOG

Customer Name _____

Customer Number _____ Invoice Number: _____

Date _____ Time: _____

Number of Boxes: _____ Number of bags: _____

Courier Service Name: _____

Driver's Name (print): _____

Driver's Signature: _____

Driver's License Number: _____ State: _____

Driver ID# (Cab Number, etc.) _____

WILL CALL LOG

Customer Name _____

Customer Number _____ Invoice Number: _____

Date _____ Time: _____

Number of Boxes: _____ Number of bags: _____

Courier Service Name: _____

Driver's Name (print): _____

Driver's Signature: _____

Driver's License Number: _____ State: _____

Driver ID# (Cab Number, etc.) _____

CardinalHealth

FA07.00

DELIVERY VEHICLE SECURITY

The following rules are intended to promote safety and security for drivers and their delivery vehicles. They are to be complied with at all times.

1. Keep all merchandise in the rear of the truck. Leave nothing in the cab.
2. Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
3. Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.
4. Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
5. If you break down, stay with your truck. Leave only to call for assistance.
6. Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.
7. In the event of a robbery:
   a. Offer no resistance.
   b. Stay calm.
   c. Be observant.

Driver Signature: _____

Witness Signature: _____

Date: _____

Cardinal Health

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA08.00

TITLE: Personnel

ISSUE DATE: 6-15-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA08.00**
TITLE: Personnel	**ISSUE DATE:**
	PAGE: 2 of 3

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for screening and training of personnel.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Pre-Employment Screening

a.) All prospective employees shall be drug tested and be the subject of a criminal background investigation.

2.) Controlled Substance Requirements

a.) Anyone allowed unsupervised access to the cage or vault in order to perform job functions shall:

i.) Be trained using the **Training Manual For Employees Handling Controlled Substances (Exhibit EA08.00)**.

ii.) Complete the **Test for Distribution Center Employees Handling Controlled Substances (Exhibit EB08.00)**.

iii.) Complete a **Security Information Sheet (Exhibit FA08.00)**.

b.) The test and form must be submitted to the Corporate Compliance Department.

i.) The department will grade the test and each individual must pass with a score no lower than 88%.

ii.) If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score.

CardinalHealth CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL	POLICY NO: DEA08.00
TITLE: Personnel	ISSUE DATE:
	PAGE: 3 of 3

c.) The employee must be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed.

d.) The results of the background check along with the individual's test score will be shared with distribution center management.

e.) The background check must be performed prior to the distribution center manager assigning the employee to the controlled substance area.

EA08.00

TRAINING MANUAL FOR EMPLOYEES HANDLING CONTROLLED SUBSTANCES

Training Manual
TABLE OF CONTENTS

INTRODUCTION

The Drug Enforcement Administration (DEA) is the primary federal law enforcement agency charged with combating drug abuse in this country. Established in 1973, it is a combination of the agencies formerly known as the Bureau of Narcotic and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, and certain drug related elements of both the Bureau of Customs and the Office of Science and Technology. The intent of the amalgamation of agencies is to eliminate the piecemeal approach to the control of narcotics and dangerous drug and, by coordinating the effort, to control more effectively narcotic and dangerous drug activity and abuse.

Prior to this amalgamation of agencies, the laws on the control of drugs were collected and conformed into one piece of legislation, the Comprehensive Drug Abuse Protection Control Act of 1970 (the "Controlled Substance Act"). This act consolidated over 50 pieces of legislation that had been enacted in piecemeal fashion since 1914. The trust of this Controlled Substance Act is the improvement of the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by establishing a "closed" system for legitimate drug handlers so that controlled drugs can be traced from their origin to their eventual user.

The act contains nine major control mechanisms that apply to the manufacture, purchase and distribution of substances subject to the act. They are:

- registration of handlers;
- record keeping requirements;
- manufacturing quotas;
- distribution restriction;
- dispensing restrictions;
- limitations on imports and exports;
- conditions of storage of drugs;
- reports of transactions to the government; and
- criminal, civil and administrative penalties for violations.

Each of these mechanisms has a considerable impact upon the industry, especially the penalties and loss of registration provisions. Each violation of the act (which may be as little as misplacing one bottle of controlled substances) is punishable up to 15 years imprisonment and $10,000 in fines. In addition, a relatively speedy administrative hearing can result in a finding of inadequate security. Such a finding could lead to loss of registration, effectively putting a company out of the controlled drugs distribution business. It has, therefore, become a cost justified good business practice to establish effective control measures in the first instance. DEA, like most other federal agencies, prefers voluntary rather than forced compliance.

The DEA Diversion Control Program is responsible for implementing and maintaining controls over the distribution of legally produced controlled substances into the illegal market. The diversion control program operates through: periodic investigations to ensure that record keeping, reporting, and security requirements are being met; targeted investigations (for violative registrants); preregistration investigations; and organized system of destruction; manufacturing quotas; and drug scheduling (collection of abuse and diversion information). Periodic inspections are conducted as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls to guard against the diversion of controlled substances.

This manual is intended as a resource to the Controlled Substance Act and Regulations. It is intended as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business.

In addition to this manual, you should also have the following DEA publications available for ready reference:

Code of Federal Regulations 21. Food and Drugs
Part 1300 to End – *available from:*

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
(202) 783-3238

ARCOS Reporting Manual – *available from:*

United States Department of Justice
Drug Enforcement Administration
ARCOS Unit, P.O. Box 27273
Central Station
Washington, D.C. 20038-7273
(202) 307-8600

Note: The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

INVENTORY

There are specific regulations with regards to inventory. DEA requires a biennial inventory, and a year-end ARCOS inventory. As company policy, periodic inventories are recommended. Unless otherwise specified, the general requirements pertain to each type of inventory.

Biennial
(21 CFR 1304.11 (c))

Frequency. Every two years, the wholesaler is required to take a physical inventory of all controlled drug stocks on hand in live, morgue and brokerage.

When. The regular biennial inventory date is every two years from the date the wholesaler initially became registered to distribute controlled substances. Thus, for all firms who were provisionally registered on May 1, 1971, the biennial inventory date is May 1st every odd year. For any firm registered after May 1, 1971, or which has been issued a new registration since May 1, 1971, the regular inventory date is two years from the initial date of registration, e.g., Firm A which first became registered on August 21, 1974, has a regular biennial inventory date of August 21 every even year. The wholesaler may take the inventory within four days of the inventory date if he/she notifies the DEA special agent in charge in advance.

Changing Inventory Date. To coincide with a fiscal year, year-end ARCOS inventory, general inventory time, or any other reason, the wholesaler may change the controlled drug inventory date to another fixed date provided that the new is within two years of the previous biennial date. DEA does not have to be notified.

Cardinal Health had received prior authorization from DEA for all Cardinal Health locations to conduct biennial inventories on December 31 of even numbered years and will continue to do so. Refer to DEA correspondence 11/21/96.

Year-End ARCOS
(21 CFR 1304.33 (b))

Frequency. Every year, the wholesaler is required to take a physical inventory of all reportable controlled substances on hand in live, morgue and brokerage.

When. The inventory must report the stock on hand as of the close of business on December 31st.

Reporting. A report of the inventory shall be filed with the ARCOS Unit of the DEA by January 15th of the following year.

Periodic

(21 CFR 1304.11)

Frequency. A daily count of controlled substances and narcotics having movement (sales, purchases, and returns) on the previous day shall be conducted, and a monthly count of all controlled substances in the facility.

When. Counts shall be conducted as close to the end of day processing so as not to interfere with the current day's business. The monthly count shall be conducted as close to the same time each month as possible.

General Requirements

Newly Controlled Drugs. An initial inventory must be taken of all stocks on hand of a newly controlled drug on the effective date of control. Subsequently, the newly controlled drug will be reinventoried on the same date as all other controlled drugs. **(21 CFR 1304.11 (d))**

Note: Many wholesalers have been cited for missing the initial inventory date on newly controlled drugs. For example, anabolic steroids were controlled (Schedule III) effective February 27, 1991, and an initial inventory should have been taken on that date.

Drugs to Be Included. All controlled substances on hand as of the inventory date must be included. Returns, damaged goods, and any other drugs awaiting disposal must be inventoried.

Note: Wholesalers often overlook returns and drugs awaiting disposal in taking inventory.

Required Inventory Records. The inventory must be maintained in written, typewritten, or printed form. It must be signed by those taking the count and both the date of the inventory and whether it was taken as of the opening of business or close of business must be recorded. Inventories of all Schedule I (research drugs) and Schedule II substances must be separated from inventories for all other substances. Schedule III through V substances may be maintained separately from all other substances or in a readily retrievable manner. Readily retrievable means that the records (whether ADP, electronic, or mechanical are kept in such a manner that they can be separated out in a reasonable time and/or the items are identifiable visually from other items appearing on the records (asterisk, redlined, etc.).

For each controlled substance in finished form, the required inventories must contain:

- Name of the substance;
- Each finished form (e.g., 10-mg. tablet or 10-mg. concentration per fluid ounce or milliliter;
- Number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- Number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

For controlled substance returns, damaged goods, or substances awaiting disposal, the inventory must contain:

- Name of the substance;
- Total quantity of the substance to the nearest metric unit of weight or the total number of units of finished form; and
- Reason for the substance being maintained by the registrant.

(21 CFR 1304.22 (b), 21 CFR 1304.11(2))

Count Requirements. When taking an inventory, the following steps shall be taken,

- Do not allow any product into or out of the area during the count or recount.
- Counts shall be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager shall sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Retention of Inventory Records. The records must be retained for three years from the date the inventory was taken and must be available for DEA inspection at the registered location where the inventory was made. **(21 CFR 1304.04)**

Note: State record keeping requirements may be more than three years and records must be maintained accordingly.

DEA REGISTRATION

Detecting Fraudulent Registration Numbers

A DEA registration number consists of a two-character prefix and a seven-character suffix which are determined as follows:

Prefix. 1st character is A or B for all practitioners, hospitals, pharmacies and teaching institutions; it is P or R for all other classes of registrants. M is used for mid-level practitioners (MLP). The 2nd character is the first letter of the registrant's last name if an individual, or the first letter in the first word of the name if a firm (Note, a "9" is inserted in this position if the firm's name begins with a number—e.g., "101 A Street, Inc.").

Suffix. The suffix contains seven numeric characters, the seventh of which is a check digit that is determined as follows:

Add the number of the 1st, 3rd and 5th characters to twice the sum of the 2nd, 4th and 6th characters; if the total is a single-digit number, that number is the check digit; if the total is a two-digit number, the digit in the ones column is the check digit and is inserted in the seventh position.

Checking Expiration Dates

A system to verify the renewal of registration number can be standardized by expiration date because all registrations with the same second character in the prefix expire on the same date. The expiration dates for these characters are:

January 31	M	July 31	B
February 28	S	August 31	C, E
March 31	L, P	September 30	F, G
April 30	Q, R, 9	October 31	H, N
May 31	U, V, W, X, Y, Z	November 30	I, T
June 30	A, D	December 31	J, K, O

Note: Practitioners, hospitals, pharmacies, and teaching institutions re-register every three years. All others register annually.

DEA Registration Verification

(21 CFR 1301.74(a))

The wholesaler is responsible for verifying that customers possess a valid, current **DEA Certificate of Registration.** DEA will not verify routinely, and it is left to the wholesaler to develop a system. There are several methods the wholesaler may use.

Cardinal Health's policy and procedure requires that new accounts provide a photocopy of a current DEA registration prior to being allowed to purchase controlled substances. A copy of the account's state license must be obtained at the same time.

Registration expiration dates for existing accounts are monitored on a monthly basis. Those accounts whose registration is due to expire are contacted either by letter, telephone, or sales representative and are requested to provide an updated copy of their registration. A copy of the state license must also be requested.

In addition, the computer system prohibits the purchase of controlled substances by any customer who does not have a DEA registration number loaded into the computer system or whose registration has expired. The system also limits the purchase of controlled substances to the schedules for which the customer is registered. Most customers are registered for schedules 2, 2N, 3, 3N, 4, 5.

Cardinal Health purchases, on a quarterly basis, a tape from the DEA of all current registrations. This tape is run against each division's customer database. The **Quarterly DEA Exception Report** is a listing of all customers in a division's database whose DEA number or expiration date does not match the DEA database. Review and maintenance of this report must be done to assure sales of controlled substances are only made to current registrants of the DEA.

Questioned Registrations

Whenever there is reason to question a customer's registration (i.e., the number does not pass the check digit, there is a question whether the registration includes the schedule(s) ordered or a pharmacy has changed hands and the new owner is using the old DEA number), further inquiry must be made to ensure that the customer is properly registered. The local DEA office **will** check this type of situation. Calls to the local DEA office shall be documented on a **Regulatory Agency Contact Form.**

Delayed Registration Renewal Certificates

From time to time, computer delays at DEA cause customer renewals to be late, even though renewal applications were submitted in a timely fashion. When the customer tells the wholesaler that this has occurred, the wholesaler shall contact the local DEA office to confirm this fact and to authorize continued shipments. If the authorization is made by telephone, the wholesaler shall write down the confirmation, including the name of the authorizing DEA official, the date, and the details of the authorization. Document this on a **Regulatory Agency Contact Form.**

Modification of DEA Registration

When a registrant moves to a new location, they must have the new location inspected by the DEA and obtain a new DEA registration with a corrected address. Many customers continue to use the old registration and expect that their controlled substance orders will be delivered to the new address. This is a violation of DEA regulations. Controlled substances can only be shipped to properly registered location and only to the address listed on the registration. **(21 CFR 1301.51)**

Transfer of Ownership

For a change of pharmacy ownership and continuing operation on a previous owner's DEA registration, the primary condition is that both the buyer and seller enter into a **Limited Power Of Attorney** that specifically sets forth the following:

- The seller agrees to allow the controlled substance activities of the pharmacy to be carried out under the seller's DEA registration;
- The seller agrees to allow the buyer to carry out the controlled substance activities of the pharmacy, including the ordering of controlled substances, as an agent of the seller;
- The seller acknowledges that, as the registrant, they will be held accountable for any violations of controlled substance laws which may occur; and
- The buyer agrees that the controlled substance activities of the pharmacy may be carried out under the seller's registration for no more than 45 days after the purchase date, which shall be recorded in the agreement.

Prior to selling product to the new owner, you must obtain a copy of the **Power Of Attorney** and file it with the copy of the previous owner's DEA registration certificate.

In addition, you must monitor the 45-day limit on controlled substance activity imposed as part of this policy.

Termination of DEA Registration

(21 CFR 1301.52)

The closing of a facility requires that a DEA certificate of registration be terminated. At least 14 days prior to close and controlled substance transfer, submit a registered or certified letter, return receipt requested, to local DEA supervisor containing the following information:

- name, address, registration number of distribution center which is transferring the controlled substances and associated records and terminating the registration,
- name, address, registration number of distribution center to whom the controlled substances and associated records will be transferred,
- date of the controlled substance transfer and a description of the proposed transfer procedure,
- date and time of termination.

Contact state licensing agencies and follow their specific procedures for registration termination.

On the date of the transfer, a complete inventory of all controlled substances being transferred must be taken. A copy must be maintained with the records for each distribution center. The transfer must be documented as a purchase and sale. Purchase orders, 222's, invoices and receiving documents must be created.

The Corporate Compliance Department will arrange and supervise the transfer of all controlled substances.

Upon termination of the registration, submit to the regional DEA office by registered or certified mail, return receipt requested, a cover letter and the following:

- DEA Certificate of Registration,
- unused DEA Forms 222.

Chemical Registration

Any person or persons who distribute products covered by the Methampetamine Control Act (ephedrine, pseudoephedrine, phenylpropanolamine) must have either a controlled substance registration or a chemical registration. They do not have to possess both registrations. Registrations must be renewed annually.

A DEA chemical registration number consists of a six character prefix and a three character suffix which are determined as follows:

Prefix. The prefix contains six numeric characters. There is no check digit as in a controlled substance registration.

Suffix. The suffix contains three alpha characters. The first is the first letter in the registrants name. The second is a random letter and the third identifies the activity of the registrant as listed below.

W - Manufacturer

Y - Distributor

V - Retail Distributor

X - Importer

Z - Exporter

ORDER FORMS

(21 CFR 1305)

All transactions of Schedule I and II substances must be made on federal order forms - **DEA Form 222.** Any exceptions to this requirement must be approved by DEA on a case-by-case basis. Purchases from vendors and returns from customers are executed on order forms issued by Cardinal Health. Sales to customers are executed on order forms issued by the customer.

Obtaining and Executing Order Forms

Only persons registered to handle Schedule I and/or II substances may obtain order forms. Order forms may be executed only on behalf of the registrant named on the order form provided that the registrant **currently** is registered to handle the scheduled substances ordered.

When blanks are received from the DEA, the order form numbers must be logged on the **DEA Narcotic Blank Log (Form #4),** and kept in the vault for safekeeping, pending use.

Separate Records Requirement

DEA has taken the position that order forms are the primary record of Schedule II transactions and, therefore, that the maintenance of order forms in a separate file satisfies the requirement that records of Schedule II transactions be maintained separately. Secondary records (e.g., invoices accompanying order forms) are not required to be maintained separately.

Purchases and Returns of Schedule I and II substances

Procedure for Executing Order Forms

(21 CFR 1305.06)

- The purchaser simultaneously prepares and executes order forms in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms are prepared by use of a typewriter, pen or indelible pencil. A wholesaler may consider rejecting any Form 222 completed in pencil, indelible or not, as the identification of indelible over regular lead is tenuous at best.

- Only one item is entered on each numbered line. There are 10 lines on each order form. Some registrants still are using the old five-line order forms, which are valid.

If one order form is insufficient to include all items in an order, additional forms are used. The last line completed is noted on that form in the space provided. This number must correspond to the number of lines used. For example, if two lines are

used on an order form to describe one item, the number of lines completed at the bottom is two.

- An item consists of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item is made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item, the form must show the name of the product ordered, the finished or bulk form of the product (e.g., 10-mg. tablet, 10-mg. concentration per fluid ounce or milliliter or U.S.P), the number of units or volume in each commercial or bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the product if not in pure form. The catalogue number of the product may be included at the discretion of the purchaser.

- The correct name and address of the supplier from whom the controlled substances are being ordered is entered on the form. Only one supplier may be listed on any one form.

- Each order form is signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to **21CFR 1305.05(c).** The name of the purchaser, if different from the individual signing the order form, is inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspection or to enforce any federal, state or local law regarding controlled substances.

Centralized Purchasing of Schedule II Drugs

When the ordering of schedule II drugs and the processing of the DEA Forms 222 is handled by Corporate Purchasing, the following steps are taken:

- Corporate Purchasing orders DEA Form 222's by contacting the appropriate DEA office or the DEA Registration Unit in Washington, D.C., or by completing a 222 Requisition Form.

  Note: All 222 Requisition Forms received by the divisions must be forwarded to Corporate Purchasing.

- Order Form Books are received at the division.
- The division logs the order form numbers onto the **DEA Narcotic Blank Log.**
- Division retains adequate supply of order forms for emergency purchases and customer return buybacks and forwards remainder to Corporate Purchasing, along with a copy of the **DEA Narcotic Blank Log.**
- Corporate Purchasing receives and stores order forms in a secure area. Corporate Purchasing contacts division if numbers are out of sequence or an order form is missing.
- Corporate Purchasing creates Schedule II purchase order and completes order form according to DEA regulations **(21 CFR 1305.06).**

- Copy 1 (brown) and Copy 2 (green) copies of order form are mailed to the vendor; Copy 3 (blue) is mailed to the division. Corporate Purchasing makes copy of the order form for purchasing records.

  Note: All three copies of voided order forms must be sent to the division.

- Corporate Purchasing adds order form numbers to purchase orders and transmits purchase order file to the division.
- Division receives Copy 3 (blue) copy of order form and records appropriate information onto **DEA Narcotic Blank Log**. Division contacts Corporate Purchasing if numbers are out of sequence or an order form is missing.

Power of Attorney

(21 CFR 1305.07)

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a **Power of Attorney (Form #2)** for each such individual. The **Power Of Attorney** is signed by the same person who signed or was authorized to sign, the most recent application for registration or re-registration and by the individual being authorized to obtain and execute order forms. The power of attorney is filed with the executed order forms of the purchaser, and retained for the same period as any order form bearing the signature of the attorney. The power of attorney must be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a **Notice Of Revocation (Form #3),** signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, or by whomever signed the most recent application for registration or re-registration, and filing it with the power of attorney being revoked.

Sales of Schedule I and II Substances

Procedure for Filling Order Forms

(21 CFR 1305.09)

- The purchaser submits copy 1 (brown) and copy 2 (green) of the order form to the supplier and retains copy 3 (blue) in his/her own files.

  Note: Order forms given by customers to contract drivers for eventual delivery to the distribution center must be in a sealed envelope. The driver must have no knowledge of the contents of the order form. ***Refer to DEA Correspondence 07-18-96.***

- The supplier fills the order, if possible and if the supplier desires to do so, and records on copies 1 (brown) and 2 (green)the number of commercial and bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days after its execution by the purchaser, except as noted below.

- The controlled substances are shipped to the purchaser at the location printed by the administration on the order form, except as noted below.

- The supplier retains copy 1(brown) of the order form for his/her own files and forwards copy 2 (green) to the special agent in charge of the DEA field office in the area in which the supplier is located. Copy 2 (green) is forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy 2 (green) is forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

- The purchaser records on copy 3 (blue) of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Note: Order forms submitted by registered procurement officers of the Armed Services Medical Procurement Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the order forms, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Note: DEA Policy is that the wholesaler or a "direct proprietary agent" of the wholesaler must have the order form in hand before the product is released. The direct proprietary agent can be a sales representative, a depot supervisor or a driver (not common or contract).

Substitutions

It is acceptable to substitute generic product for generic product, generic product for brand name product, or brand name product for generic product provided that the products are equivalent, the name and the NDC number of the actual product shipped are reflected on the order form, and the purchaser agrees to the substitution.

Faxing Narcotic Order Forms

DEA, as a matter of policy, has stated that they will allow the faxing of order forms when it involves a direct transmission from the customer to the wholesaler; however, the order may not leave the distribution center until the original order form arrives at the distribution center or is in the possession of a direct proprietary agent of the wholesaler. DEA may grant approval in emergency situations on a case-by-case basis for shipping the order before receiving the order form.

The DEA is also not opposed to having order forms faxed from depots to the wholesaler when the following conditions are met:

- The original order forms, when delivered to the depot, are in the possession of an employee of the wholesaler who is familiar with order form regulations.

- The order forms and a **DEA 222 Transmission Log** are faxed to the division and order form receipt is verified to the log.
- Narcotic orders are **not** released at the depot unless there is a corresponding order form.
- The regulatory requirements for the processing of DEA Form 222 are strictly adhered to.

This procedure **shall not be used unless** the depot operation is supervised by a Cardinal Health employee, the Cardinal Health employee faxes the order forms, and the Cardinal Health employee maintains possession of the original order forms until the order forms are exchanged for the controlled substances.

DEA **will not permit**, under any circumstances, the faxing of order forms from contract carrier crossdock locations by contract carrier employees.

The faxing of 222s for customers serviced by contract carriers must be handled as follows:

FROM THE CROSSDOCK:

1. Contract delivery drivers deliver original 222s in sealed envelopes to contract carrier crossdock supervisor.

2. Crossdock supervisor delivers sealed envelopes containing 222s to Cardinal Health crossdock employee.

3. Cardinal Health crossdock employee removes 222s from envelopes and **completes DEA 222 Transmission Log**.

4. Cardinal Health employee faxes 222s to distribution center. **This must be done using one transmission and the DEA222 Transmission Log must be the last page of the fax.**

5. Fax is received in distribution center by Operations Manager or designee.

6. Operations Manager or designee verifies faxed 222s received with information on the DEA 222 Transmission Log. Faxed copies of 222s are checked for legibility and compliance and are processed according to DEA regulations.

    a) If any discrepancies exist that would require 222s to be re-faxed, Operations Manager or designee contacts Cardinal Health crossdock employee.

7. Cardinal Health crossdock employee places original 222s in a sealed envelope for delivery to the distribution center.

8. Operations Manager or designee delivers faxed 222s to the vault.

9. Vault clerk fills orders and files faxed 222s. Orders are held until original 222s arrive at the distribution center and are compared to the orders.

FROM THE CUSTOMER:

1. Customer faxes 222 directly to the distribution center.

2. Operations Manager or designee checks 222 for legibility and compliance and processes according to DEA regulations.

a) If any discrepancies exist that would require 222 to be re-faxed, Operations Manager or designee contracts the customer.

3. Customer gives original 222 to contract delivery driver in a sealed envelope for delivery to distribution center.

4. Operations Manager or designee delivers faxed 222 to the vault.

5. Vault clerk fills order and files faxed 222. The order is held until the original 222 arrives at the distribution center and is compared to the order.

Preservation of Order Forms

(21 CFR 1305.13)

- The purchaser retains copy 3 (blue) of each filled order form. The purchaser also retains in his/her files all copies of each unaccepted or defective order form and any statements attached to them.

- The supplier retains copy 1 (brown) of each order form that has been filled.

- Order forms must be maintained separately from all other records of inspection for three years (as are all records of controlled substance transactions). If a purchaser has several registered locations, copy 3 (blue) of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to **(21 CFR 1305.06 (d))** must be kept at the registered location printed on the order form.

  Note: State record keeping requirements may be more than three years and records must be maintained accordingly.

Unaccepted and Defective Order Forms

(21 CFR 1305.11)

Federal regulations applicable to the handling of such order forms are as follows:

- No Order Form shall be filled if it:

  (1) Is not complete, legible, or properly prepared, executed, or endorsed; or

  (2) Shows any alteration, erasure, or change of any description.

- If an Order Form cannot be filled for any reason under this section, the supplier shall return Copies 1 (brown) and 2 (green) to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept the order; a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

- When received by the purchaser, Copies 1 (brown) and 2 (green) of the Order Form and the statement shall be attached to Copy 3 (blue) and retained in the files of the purchaser in accordance with **21 CFR 1305.13**. A defective Order Form may not be corrected; it must be replaced by a new Order Form in order for the order to be filled.

- Any information which is pre-printed on the order form must not be altered in any way.

Pursuant to these regulations, order forms shall be returned to the customer under the following circumstances:

- The writing is illegible or it is otherwise impossible to identify a customer's registration number, items specified or quantities, or there is improper execution or endorsement.
- There are alterations, erasures, or changes resulting in questions regarding the identity of the customer, customer's registration number, items or quantities.
- Signatures are omitted.
- Sixty days have elapsed from the date of execution by the purchaser.
- The last line completed is greater than the last line specified.
- The number of line items is greater than the total number of items specified.
- Customer voids a line.
- "Last Line completed" is omitted.

Federal order forms which identify the customer's registration number, items and quantities, and which are properly signed but are incomplete or have minor errors may be corrected to the following extent:

- The supplier's name, address, city, state, or zip code may be added when omitted by the customer.
- The supplier's address, city, state or zip code may be corrected.
- The date of the order may be added when omitted. Whenever possible, the postal date on the envelope shall be used.
- It is permitted to add or change hydrochloride, sulfate, phosphate, ampules, tablets, etc. if the customer's order is correct in all respects except that it is specified in error; for example, specifies capsules and the product requested is properly designated and supplied in tablets.
- A letter or digit in the National Drug Code designation may be corrected if the controlled substance is described correctly, or the strength stated may be corrected if the quantity of controlled substance is not increased in any way.

- Order forms may be accepted when the customer has sent all three copies of the form to the supplier, but the customer's copy must be forwarded to him in advance of the shipping product.
- Order forms received by the supplier without interleaf carbon may be accepted, but the supplier must insert a replacement carbon between the forms before making any entries on the form.
- If a form is received which lists a package amount which is unavailable, a lesser amount may be shipped (e.g. order is for package size 100, if unavailable may ship package size 50), or if a form is received which lists a package amount which is unavailable, different package sizes not to exceed the original amount may be shipped (e.g. ordered 1 x 1000, may ship 10 x 100).
- Lesser number of line items ordered than line items specified, if the supplier crosses out the remaining lines before filling the form.
- Last line completed has been incorrectly noted. The order form should not be rejected when it is clear that this is due to misinterpretation, rather than an attempt to facilitate diversion.

A single item must be canceled for the following reasons, but the balance of the order may be shipped:

- If the number of packages, size of package, or strength has been altered by the person preparing the order form.
- If the item requested is discontinued or not listed, or is a non-controlled substance or is a controlled substance other than a Schedule I or II controlled substance.
- Strength is dittoed on the order form rather than designated.
- Strength is omitted (except trademark items when National Drug Code numer is listed).
- Size of package incorrectly stated (quantity may be reduced).
- Size of package omitted.
- When a multiple item order is properly prepared and complete in all other respects but a single item has a non-correctable defect, this item may be canceled in lieu of returning the order form to the customer.

Cancellation and Voiding of Order Forms

(21 CFR 1305.15)

- A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier indicates the cancellation on copies 1 (brown) and 2 (green) of the order form by drawing a line through the canceled items and printing "Canceled" in the space provided for number of items shipped.

- A supplier may void part or all of an order form by notifying the purchaser in writing of such voiding on an **Order Form Rejection Notification.** The supplier must keep a copy of the order form and the notification. The supplier indicates the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

- No cancellation or voiding permitted by this section affects in any way contract rights of either the purchaser of the supplier.

Narcotic Order Form Review

The DEA has established specific criteria for the acceptance of Narcotic Order Forms. To assure that the appropriate personnel receive continuous training with respect to these regulatory requirements, the previous day's Narcotic Order Forms must be reviewed for compliance with DEA regulations. Complete a **Narcotic Order Review Form (Form #7)** for any order forms that were processed in violation of DEA regulations. Discuss violations and the appropriate responsive action with personnel involved. File the Narcotic Order Review Form with a copy of the corresponding DEA Form 222.

Procedure for Endorsing Order Forms

(21 CFR 1305.10)

- An order form made out to any supplier who cannot fill all or part of the order within the time limitation set forth in 1305.09 may be endorsed to another supplier for filling. The endorsement is made only by the supplier to whom the order form was first made, states (in the space provided on the reverse sides of copies 1 (brown)and 2 (green) of the order form) the name and address of the second supplier, and is signed by the person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier fills the order if possible and if the supplier desires to do so, in accordance with **21 CFR 1305.09(b),(c) and (d)** including shipping all substances directly to the purchaser.

- Distribution made on endorsed forms is reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier records the name, address and registration number of the first supplier.

Lost or Stolen Order Forms

(21 CFR 1305.12)

- If a purchaser ascertains that an unfilled order form has been lost, the purchaser must execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods ordered in the first order form were not received through loss of that order form. Copy 3 (blue) of the second order form and a copy of the statement are retained with copy 3 (bue) of the order form first executed. A copy of the statement is attached to copies 1 (brown) and 2 (green) of the second order form sent to the supplier. If the first order form

subsequently is received by the supplier to whom it was directed, the supplier marks it as "Not accepted" and returns copies 1 (brown) and 2 (green) to the purchaser, who attaches it to copy 3 (blue) and the statement.

- Whenever any used or unused order forms are stolen or lost (besides in the course of transmission) by any purchaser or supplier, immediately upon discovery of the theft or loss, that person reports it to the local office of the Drug Enforcement Administration stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers. If an entire mailing envelope of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms it contained, the purchaser must report, in lieu of the numbers of the forms contained in the envelope, the date or approximate date the envelope was issued. If any unused order form reported lost or stolen subsequently is recovered or found, the Registration Unit must be notified immediately.

Return of Unused Order Forms

(21 CFR 1305.14)

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address shown on the registration), or is suspended or revoked (pursuant to **21 CFR 1301.45** or **1301.46** of this chapter), the purchaser (or his/her executor) must return all unused order forms for controlled substances listed in Schedules I and II for which the purchaser is registered to the nearest DEA office.

REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

When	
Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

- **ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) must be sent to:**

  DEA Headquarters
  Attn: ARCOS Unit
  2401 Jefferson-Davis Highway
  Alexandria, VA 22301

- **ARCOS reports sent via the U.S. Postal Service must use the following address:**

  Drug Enforcement Administration
  ARCOS Unit
  P.O. Box 27273
  Washington, D.C. 20038-7273

Optional ARCOS Reporting Modes

Registrants using punched card accounting machines or electronic data processing equipment must submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual **ARCOS OCR Form - DEA Form 333.**

Reporting ARCOS Data from Another Location

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

DEA Order Forms

(21 CFR 1305.09 (d))

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

Drug Thefts/Losses

(21 CFR 1301.74(c))

The registrant notifies by telephone the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss. A **Report of Theft or Loss of Controlled Substances -DEA Form 106** must also be completed and submitted to DEA within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** must also be submitted to ARCOS.

Note: Some state agencies require copies of all DEA Forms 106 filed with DEA. See Exhibit S for State reporting requirements.

Drug Destructions

(21 CFR 1307.21)

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler must notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

Cardinal Health has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**.

DEA Form 41 shall also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident.

Suspicious Orders

(21 CFR 1301.74(b))

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

Establishing Suspicious Order Criteria

Wholesalers must establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Health facility submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel shall be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA must be notified, if possible, before the order is shipped and a copy of all such orders must be maintained in the facility's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's Pharmaceutical Distribution retail customers and Boston's Pharmaceutical Distribution hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts must be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items must be posted at the product locations.

STRUCTURAL SECURITY

Schedule II Controlled Substances
(21 CFR 1301.72)

Schedule II controlled substances are stored in a vault, the physical structure of which meets the following specifications or equivalent:

If grandfathered (a vault constructed before, or under construction on, September 1, 1971): substantial construction with a steel door and a combination or key lock.

A vault constructed after September 1, 1971: walls, floor and ceiling constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

The door and frame unit of the vault (GSA approved, Class V) conforms to the following specifications, or the equivalent:

- 30 man minutes against surreptitious entry;
- 10 man minutes against forced entry;
- 20 man hours against lock manipulation; and
- 20 man hours against radiological techniques.

DEA will also approve, on a case by case basis, UL listed Class M modular vaults for the storage of Schedule II controlled substances.

If operations require the vault to remain open for frequent access, then it must be equipped with a 'day gate' that is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove material in the morning and return material at night, and is always relocked immediately after use, a 'day gate' is not required.

Schedule III, IV, and V Controlled Substance Storage

DEA regulations **(21 CFR 1301.72(b))** provide that Schedule III through V controlled substances must be secured as follows:

- In a cage located within the building on the premises meeting the specifications in **1301.72(b)(4)(ii-iv)** and Section **1301.72 (b)(3)(ii)(a)(b)**, which read as follows:

21 CFR 1031.72(b)(4):

- A cage, located within a building on the premises, meeting the following specifications:
- Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

  (a) At least one inch in diameter;

  (b) Set in concrete or installed with lag bolts that are pinned or brazed; and

  (c) Which are placed no more than 10 feet apart with horizontal one and one half inch reinforcements every sixty inches;
- Having a mesh construction with openings of not more than two and one half inches across the square.
- Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height.
- Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of **21 CFR 1301.72(b) (3)(ii).**"

21 CFR 1301.72(b)(3):

- Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination

- The controlled substance section also provides:
  The track holding sliding 10-gauge steel gates in place is adjusted to meet self-closing requirements and the track is "trapped" to prevent the gate from being lifted out of the track surreptitiously.

  Alternate: Where swinging cage doors are installed, hinges are properly secured.

Note: Schedule III through V controlled substances may be stored with Schedule II controlled substances under security measures previously described for Schedule II controlled substances.

Non-controlled substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by **21 CFR 1301.72(b)** *provided that permission for such storage of noncontrolled items is obtained in advance in writing from the Special Agent in Charge of DEA for the area in which storage area is situated. Any such permission tendered must be upon the Special Agent's written determination that such non-segregated storage does not diminish security effectiveness for Schedule III through V controlled substances. This authorization must be posted, in plain sight, in the secured area. An additional copy of the authorization letter must be retained by division management.*

Company Vehicles

Vehicles used for the delivery and pickup of controlled substances are equipped with proper vehicle locks including, when appropriate, padlocks for cargo doors.

ACCESS CONTROL

General Warehouse

It is the policy of Cardinal Health to limit access to the general warehouse to only those employees who have a full-time work assignment that requires their presence in the warehouse. Each division shall maintain a list of employees authorized to have warehouse access. This access shall be controlled by a Card Entry Access Control System.

Specifically excluded from warehouse access without a full-time escort are the following groups of people:

All visitors including:

- Vendor sale representatives
- Cardinal Health sales representatives
- Management employees except those directly responsible for supervision of employees whose duties require them to be in the warehouse to perform their jobs
- Office employees except those whose duties require their presence in the warehouse.

Signs must be posted on all warehouse entrances regarding limited access.

Outside contractors shall be monitored through a cooperative effort of warehouse supervisory personnel and full-time warehouse employees.

Employees of Cardinal Health who require temporary access to the warehouse may be issued "temporary passes" controlled by the Distribution Center Manager or his/her designee.

Controlled Substance Area

DEA regulations related to accessibility to storage areas state:

> "The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specially authorized in writing." **(21 CFR 1301.72(d))**

Facility management maintains an **Access and Surveillance List** of those employees whose responsibilities include authorization to access the vault or cage during the open-for-business period. Only those individuals are assigned a key or knowledge of a combination. The authorized access list must be posted along with a **"Restricted Area"** sign on the door(s) of the vault and cage.

Temporary employees must never be allowed access to the cage or vault, supervised or unsupervised.

Computer System

The computer system must include security levels to prohibit access to certain files unless an employee's job responsibilities warrant access. Employees shall keep passwords to themselves and periodically change them to prevent access by others. Access must be limited for inventory adjustments, customer licensing information and financial records.

Computer room access must be controlled and limited to only those employees who have a full time work assignment that requires access to the computer room.

PROCEDURAL SECURITY

Receiving

Upon receipt, controlled substance items are physically checked by a receiving clerk. The quantity and description of the materials received are checked against the packing list provided by the vendor and against the controlled substance purchase order. The paperwork is signed and dated by the receiving clerk.

Any variations in quantities or visible damage to cartons are subject to immediate investigation. The matter must be reported to the supervisor prior to the departure of the carrier's representative from the area.

The carrier's representative is required to sign a statement written on the receiving report, describing the shortage, damage, etc. The receiving procedures must be verified by the receiving department supervisor if the actual receiving is handled by a designated employee.

If a discrepancy is noted and cannot be reconciled, the manufacturer(s) is contacted immediately by telephone and confirmation of the shortage or damage is verified in writing on the appropriate form. The loss of controlled substances is to be promptly reported to DEA. **Refer to Drug Thefts/Losses within Required Reports to DEA.** The supplier is responsible for reporting in transit losses of controlled substances by the common or contact carrier selected pursuant to **21 CFR 1301.74 (e)** upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances subsequently are recovered and/or the responsible parties are identified and action taken against them (21 CFR 1301.74c).

Immediately on verification of the order received, the controlled substances and the corresponding paperwork are placed in a rolling locked cage and moved to the vault or to the controlled substance cage. No controlled substances may be left in the receiving area overnight or during periods when the receiving area is not under adequate surveillance.

Stocking

Verify all products and quantities against paperwork. Date and sign each purchase order. Bring discrepancies to the attention of the supervisor immediately. Forward original paperwork to appropriate department for data entry. Retain a copy in the controlled substance area.

For Schedule II items, the product is also verified against Copy 3 (blue) of the DEA order form. The date received and quantity received columns of the order form are completed and the Narcotic Order Blank Log is also updated.

Order Filling

For Schedule III, IV, V controlled substances, the order filler picks the items and quantities as requested on the picking document. As items are picked, each line of the picking document is initialed. The completed order and paperwork is staged pending verification.

For Schedule II controlled substances, the order form - DEA Form 222 - is reviewed for accuracy, then matched to the picking document to make sure all items agree. The items and quantities are picked as requested on the picking document. The picking document is initialed as each item is picked. The completed order and paperwork is staged pending verification. The following fields on the order form must be filled in:

- Packages Shipped
- Date Shipped
- Supplier DEA Registration Number

Quality Control

All controlled substance orders must be double checked for accuracy. The quality control clerk matches the items against the picking document and initials the paperwork. The merchandise and copy of the picking document are put in a bag and sealed - preferably a heat-sealed poly bag. The other copy of the pick document is retained at the division per division policy. The outside of the package must be labeled with the name of the customer. There must be no marks identifying the contents as controlled substances. The order is then staged within the controlled substance area until shipped.

Shipping

While most regular orders are manifested on the shipping dock, controlled substance orders are manifested in the cage or vault. Controlled substance packages are not to be left unattended in the shipping department. Product may be placed in locked roll-around cages or left in the controlled substance area until the delivery person is on the premises and ready to sign for them.

Delivery

The driver is required to obtain a customer signature for any packages delivered. The proof of delivery (manifest) is then returned to the carrier or division and retained per division policy.

Returns from Customers

All returns of controlled substances must be accompanied by a return authorization. The shipments must be distinguished from the other returns without revealing their contents to the delivery drivers. Upon receipt at the distribution center, these returns are to be transferred to the controlled substance area, and processed daily, noting the actual date of receipt.

Returns of Schedule II drugs are discouraged. They must be handled by issuing an order form - DEA Form 222 - to the customer.

Partial returns of controlled substances are prohibited.

Returns to Vendors

Controlled substances returned to the vendor must be accompanied by a return authorization from the vendor and a debit memo from the division. Creating the debit memo will remove the product from inventory. Proof of delivery must be filed at the division with a copy of the debit memo.

Physical Verification of Controlled Substances

When taking an inventory, the following steps shall be taken:

- Do not allow any product into or out of the area during the count or recount.
- Counts shall be conducted from count sheet with the on hand quantities suppressed.
- Compare the inventory results with the current on-hand balance of each item.
- Recount any out-of -balance item.
- Run audit report for any out-of-balance item. The **Selected Item Audit Report** gives all movement - purchases, returns, sales and inventory adjustments - for a requested item during a specified time frame.
- Research the error, checking for orders picked but not invoiced, mispicks, etc.
- Make appropriate adjustments as errors causing variances are detected.
- The Distribution Center Manager shall sign off on the count sheet that he has reviewed all exceptions and that variances have been explained.
- File DEA Form 106, on a timely basis, for any item that cannot be resolved.
- Create ARCOS transactions for any reportable items on DEA Form 106.

Inventory Adjustments

Inventory adjustments for controlled substances shall only be made after a thorough research. Documentation must be kept on file to support any adjustments.

Breakage

Documentation of breakage occurring in the vault or cage or during delivery is strongly recommended by the DEA. Maintenance of a breakage report is designed to help control any possible intentional breakage for the purpose of removing contents. Concern should arise when the same item is broken repeatedly.

Opening and Closing

The distribution center must be opened by at least **two** employees. These employees shall meet at a safe, well-lighted, off-site location. The employees shall then proceed to the distribution center and one employee shall enter the distribution center while the other employee waits outside for an "ALL'S CLEAR" signal (the moving of blinds or flickering of lights, etc.). This procedure shall be reversed when closing the distribution center. If the utilization of two employees at opening and closing time is totally impractical, one employee opening or closing the facility alone must have security hardware such as a portable panic button.

SHIPPING

Controlled Substance Shipping Area

Schedule II controlled substance orders are retained in the vault until the driver assigned such delivery is ready to depart the premises. At that time, the order is delivered by the vault supervisor to the driver who signs a log, circling the order number of the merchandise on the manifest. The driver then loads the packets or container into the delivery vehicle.

Schedule III through V controlled substance orders in sealed containers are held in the cage or staged in the defined controlled substance staging area under the direct supervision of the shipping department supervisor or a closed-circuit TV surveillance system. The driver assigned to the specific orders signs for the controlled substance items on a log form, circling the order number of the merchandise, and then loads the order on the delivery vehicle.

No controlled substance orders awaiting shipment are left in the shipping dock during the closed period. Such unshipped orders must be returned to the controlled substance cage at the close of business. The shipping department supervisor makes a thorough search of the shipping area prior to his/her departure from that area at the end of the business day.

Shipping Destination

DEA regulations require that controlled substances be distributed only to persons who are properly registered with DEA to possess the controlled substances and that Schedule II controlled substances only be shipped to the purchases at the location printed on the order form (DEA Form 222). Emergency will call orders are an exception to the rule.

Company Delivery Vehicles

Company employees assigned to driving delivery vehicles are screened in accordance with **21 CFR 1301.90** and Cardinal Health's policy which requires all prospective employees to consent to a drug test and a criminal record check. **Delivery Vehicle Security Rules** are reviewed, and signed by drivers.

The drivers deliver the Schedule II through V controlled substance orders to the customers and obtain a customer signature on one copy of the delivery order, which the driver then attaches to his/her manifest as proof of delivery.

Common Or Contract Delivery Vehicles

The company selects common or contract carriers that provide adequate security to guard against in-transit losses.

Further, the company takes precautions to assure that shipping containers do no indicate contents are controlled substances so as to guard against storage or in-transit losses.

When distributing controlled substances through agents, the company provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Delivery Vehicle Security Rules are provided to contract carriers for distribution to drivers. Rules are reviewed and signed by drivers.

Depots/Line Haul Shipments

The use of cross-dockings and line hauls means vehicles with larger quantities of controlled substances and other merchandise and increased vulnerability to theft and/or diversion during the run from the distribution center to the depot. To protect against internal theft that may go undetected until the orders get to the customer
level, ensure that vehicle contents are checked and signatures obtained upon pickup and delivery and that line haul vehicles are secured with a numbered seal that must be cut off or broken upon arrival at the depot.

Seal Construction Specifications

Durability A seal must be strong enough to prevent accidental breakage during normal use.

Design The design must be sufficiently complex to make unauthorized manufacture of a replacement seal difficult.

Tamperproof The seal must provide readily visible evidence of tampering and prevent reconstruction after the seal is closed; that is, a seal needs construction to make simulated locking difficult.

Individually Identifiable Identification is best accomplished by embossing serial numbers and owner identification on each seal.

Seal Accountability Procedures

Record of Application Seal numbers are entered or written on transportation documents such as bills of lading and manifests.

Time of Application Trailers must be sealed immediately after the loading is completed. Roll-up-type doors must be sealed at the loading dock. Swing-out doors must be sealed immediately after the unit is far enough away to close the doors.

Verification Seal examination and verification shall be conducted at every stop, such as docks and transfer points. Multiple stops require new seals. Persons receiving sealed shipments must examine the seal and record the number on appropriate documentation, such as a log. Retain broken seals until it is determined whether there are any discrepancies. If there are none, destroy the seal. If discrepancies are found, retain the seal pending investigation.

Freight Forwarding

The term freight forwarding facility means a separate facility operated by a registrant through which sealed, packaged, controlled substances are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. **The term does not apply to depot locations operated by common or contract carriers.**

Notification to DEA

Prior to initiating operations, a registrant must submit a written notice of intent to operate the facility, by registered mail, return receipt to the DEA offices in both the area in which the freight forwarding facility is located and the area of the registered location.

The notice must contain the following:

- Name, address, DEA number of the registered location
- Address of the freight forwarding facility
- Hours of operation
- Name of person in charge
- Security and record keeping procedures
- Whether or not returns will be processed through the facility
- Applicable state licensing requirements (contact appropriate agencies)
- Request for central record keeping authorization, if applicable

Security

All controlled substances temporarily stored at a freight forwarding facility must either be held in a segregated area under constant supervision or in a controlled substance cage. Access to controlled substances must be limited and they cannot be help for more than 24 hours. Controlled substances must be packaged in sealed, unmarked shipping containers.

Record keeping

Records documenting the distribution or return of controlled substances through the freight forwarding facility must contain the following:

- Date and time of transfer
- Number of containers transferred
- Authorized signature for each transfer

Records must be maintained at the freight forwarding facility, however a registrant may request authorization to store records centrally. The request may be made as part of the initial request to operate the freight forwarding facility.

Returns

Controlled substances returns through a freight forwarding facility must be pre-authorized and the customer must deliver the controlled substances directly to an employee or agent of the registrant.

U.S. Postal Mailing And Delivery

DEA regulations applicable to the use of the U.S. postal services state: "Controlled substances including Schedule II may be sent in any quantity by registered mail, return receipt requested, from one DEA registrant to another DEA registrant. The packaging must be in plain outer containers and give no indication of the contents."

Will Call Orders

Verification calls are to be made to the person in charge of the licensed premises for whom the order is intended and the name and description of the person picking up the order and the items included in the order are obtained.

When the individual arrives to pick up the order, the shipping supervisor checks the individual's name by asking for the driver's license and comparing the description of that provided by the person in charge of the licensed premises.

The person picking up the orders signs a **Will Call Log** that is dated and initialed by the shipping supervisor. The driver's license number and the person's name are then recorded both on the packing slip and the will call log.

Note: Many wholesalers have discontinued will call orders for controlled substances to avoid this high risk diversion exposure.

PERSONNEL

Additional information is located in the Employee Handbook.

Pre-Employment Screening

Cardinal Health requires all prospective employees to sign a **Pre-Employment Waiver** consent to a physical examination, which includes a drug test, and to an investigation made of their background and fitness for the position for which they have applied.

Cardinal Health reserves the right to immediately dismiss any employee when the results of the physical examination or drug test show signs of substance abuse and/or the background investigation reveals a history of criminal activity or other information which would deem the employee unfit for the position.

Any information associated with the physical examination or background investigation will be gathered and held in the strictest confidence by Cardinal Health in accordance with all applicable laws.

It is recommended that employment shall not commence until the results of the physical examination and drug test are received and reviewed by the appropriate management personnel of Cardinal Health.

Upon commencement of employment, the new employee will complete a **Post-Employment Security Data Information Sheet.** The completed sheet is sent to the Corporate Compliance Department to conduct a criminal record check.

Controlled Substance Requirements

When an employee is promoted or transferred it may be necessary to review his/her background, depending on the nature of the transfer or promotion. Anyone allowed unsupervised access to the cage or vault in order to perform job functions must complete the **Test for Distribution Center Employees Handling Controlled Substances** as well as the **Post-Employment Security Data Information Sheet.** The test and form must then be submitted to the Corporate Compliance Department. The department will grade the test and each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee must be advised that prior to his or her working inside the controlled substance area an in-depth background investigation will be performed. The results of this background check along with the individuals test score will be shared with division management. The background check must be performed prior to the distribution center manager assigning the employee to the controlled substance area.

Security Rules

The following list of security rules has been developed to promote a safe and secure working environment for all employees and to assure compliance with United States Drug Enforcement Administration Security Regulations.

- Possessing, dispensing, or using a controlled substance without a medical prescription or reporting to work or working under the influence of alcohol or a controlled substance without a medical prescription is strictly prohibited. If an employee requires medication which may affect their performance, they must notify their supervisor immediately. DEA regulations regarding this must be posted in the facility.

- Defacing Company property or willful negligence resulting in damage due to mishandling of merchandise or destructive abuse of machines or other Company equipment is prohibited.

- Falsifying an employment application, time card, production record, or other documents for yourself, customers, or another employee is prohibited.

- Protection of Company property is a responsibility all employees must share. Any employee discovering theft, loss, or malicious damage has an obligation to report the incident immediately to his supervisor.

- Fighting or instigating a fight with an employee, customer, or supplier while on Company property is strictly prohibited. No permanent personnel action will be taken until there is a complete investigation by Management.

- Tampering with or breaching Company security systems or policies is prohibited.

- Theft or unauthorized removal or use of Company or another employee's property is prohibited.

- Possession of firearms or illegal weapons on Company property is prohibited.

- Employees must use their own card entry access card, and access cards must not be loaned to other employees. Lost access cards must be reported to Management immediately.

- Employees must use authorized employee entrance when entering and exiting the building and must use their own access card when doing so.

- Entrance and exits to the facility are to be closed at all times, unless being used for the purpose they are designed.

- All bags, boxes, lunch boxes, containers, etc., are subject to inspection when exiting the facility. Signs to this affect must be posted throughout the distribution center. Random periodic inspections could serve as a deterrent to internal theft.

- Locker assignments and locks will be issued by Cardinal Health. Personal locks are not allowed. Locks will be subject to inspection by Management at their discretion.

- Visitor's entering the distribution center must be asked to sign in on a **Visitor's Log** indicating their name, who they represent, time in, time out, and who they are visiting at the distribution center. Each visitor must wear a badge and must be escorted during their stay.

- Warehouse access is limited to employees who have full-time assignments that require their presence in the warehouse.

- Coats and pocketbooks are not allowed in the warehouse.

- Employees are to adhere to the posted access list for the cage and vault area.

- A **Miscellaneous Security Log** must be used to document any minor security-related incidents that occur but do not need to be explained in detail.

Security rules must be distributed to all employees and a signature obtained to document receipt.

Violence Prevention Procedures

The sign entitled **Violence Prevention Procedures** must be posted in conspicuous locations throughout the distribution center. These procedures must be reviewed with distribution center employees on a routine, periodic basis. It is paramount that **all** employees know exactly what to do in case they are confronted with a possible violent situation. Additional copies of these signs may be obtained through the Corporate Compliance Department.

Driver Security Rules

Drivers are required to adhere to the following security rules:

- Test all vehicle locks each day and immediately report defects to a supervisor.
- Keep all merchandise in the rear of the truck. Leave nothing in the cab.
- Secure the truck when making a delivery. Roll up all windows, lock all doors and take the keys with you.
- Do not stop for stranded motorists. This could be a setup for a hijack. If you feel it is necessary to call for assistance, do so at your next stop.

- Make it a habit to check your rear view mirror to see if you are being followed. If you suspect that you are being followed, obtain a description of the vehicle, the license number and the occupants. Proceed to the local police station; if this is not possible, proceed to your next stop and call the local police or the office.
- If you break down, stay with your truck. Leave only to call for assistance.
- Avoid areas where the threat of theft is high (such as back doors and alleys). If something appears suspicious, do not stop.

- In the event of a robbery:
  a. Offer no resistance.
  b. Stay calm.
  c. Be observant.

Driver security rules must be distributed to all drivers and a signature obtained to document receipt.

EB08.00

Company Policy

Per the *DEA Compliance Manual*, anyone allowed unsupervised access to the cage or vault in order to pick controlled substances orders must complete the *Test for Employees Handling Controlled Substances,* the Security Information sheet and the Consent and Release form. The test and these forms must then be submitted to the Corporate Compliance Department in Dublin, Ohio. Corporate Compliance will grade the test. Each individual must pass with a score no lower than 88%. If an employee does not pass the test, he/she must re-take the test at a later date and must obtain a passing score. The employee must be advised that prior to his or her working inside the controlled substance area, an in-depth background check will be performed. The results of this background check along with the individual's test score will be shared with the Distribution Center Manager. The background check must be performed prior the Distribution Center Manager assigning the employee to the controlled substance area.

EB08.00

Test for Employees Handling Controlled Substances

Name _____

Location _____

Date _____

June 2006

Instructions

1. Complete the information requested on the cover page.
2. Answer all 33 questions completely.
3. Complete the Security Information sheet and the Consent and Release form which is included at the end of this test booklet. These forms are utilized for the background investigation portion of this testing process. If this form is not completed in full, your authorization to work with controlled substances will be delayed.
4. Return the test booklet to your supervisor or manager to be forwarded to the Corporate Compliance Department to be scored.
   (7000 Cardinal Place, Dublin, Ohio 43017)
5. The Corporate Compliance Department will notify the Distribution Center Manager, in writing, of the test score results. The Cardinal Health Security Department will conduct the background investigation and will contact you if more information is needed. This notification memo must be maintained at the distribution center for audit purposes.
6. If you have any questions involving this test or the Company's written policy and procedure in regards to the handling of controlled substances, notify the Compliance Department at (614) 757-7109.

1) There must be an authorized access list for both the cage and the vault?

True_____ False_____

2) DEA Form 41 is used in the reporting of:

a) destruction or disposal of controlled substances
b) accidental breakage of liquid controlled substances
c) both a and b
d) none of the above

3) The DEA schedules Drug Wholesalers for inspection every:

a) 1 year
b) 2 years
c) 3 years
d) They have no set schedule

4) Which color copy of the 222 Order Forms must be sent to the DEA each month?

a) blue
b) green
c) brown
d) none of the above

5) You are allowed to ship controls and narcotics to a customer who has moved as long as he notifies you by phone of his new address.

True_____ False_____

6) The DEA Form 106 is used for reporting_____of controlled substances.

7) The cage and vault must be inventoried at a minimum of :

a) daily for items with movement
b) weekly for items with movement
c) monthly for all items
d) a and c
e) b and c

EB08.00

8) You may fill a narcotic blank that has no signature?

True_____ False_____

9) The proper schedules listed on the vast majority of Narcotic Order Forms consist of Schedules (fill in the blanks):

_____ _____ _____ _____ _____ _____

10) An employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible official of the company?

True_____ False_____

11) A Narcotic Blank (DEA form 222) is good for _____ days from the date it was issued.

12) DEA fines are calculated at $_____per violation.

13) It is not necessary to have someone double check your Narcotic Orders prior to them leaving the distribution center.

True_____ False_____

14) _____is the name of the unit within the DEA that requires us to send a computer tape at the end of each month.

15) As a wholesale drug distributor governed by the Drug Enforcement Administration, Cardinal Health is required to report suspicious or excessive purchases of controlled substances.

True_____ False_____

16) Possession, use, sale or purchase of any illegal drug on the job is contrary to company policy and is grounds for immediate termination.

True_____ False_____

17) In order to accept a Schedule II return from a customer, the distribution center must first issue a narcotic blank to the customer.

True_____ False_____

18) A Regulatory Agency Contact Form should be used to document:

a) regulatory agency inspections
b) reporting of excessive purchases
c) all contact with regulatory agencies initiated by agency or division
d) all of the above

19) The day-gate doors to both the cage and the vault must be self-_____and self-_____according to Federal Regulations.

20) Controlled Substances may be left outside the approved controlled substances area overnight as long as they are left in a locked roll-around cage.

True_____ False_____

21) You may store other items inside the vault as long as you have written permission from the DEA.

True_____ False_____

22) The rule book used by the DEA to enforce regulations on the drug wholesale industry goes by the initials "C.F.R.". These initials stand for:

_____

23) The "Selected Item Audit Report" lists:

a) All receipts of a controlled substance
b) All sales of a controlled substance
c) All controlled substance adjustments
d) All transactions of a controlled substance

24) It is Cardinal Health, Inc.'s policy to thoroughly discourage returns of scheduled narcotics.

True_____ False_____

25) How often must the report entitled "Ingredient Limits Report" or "Excessive Purchase Report" be generated at your Distribution Center?

a) Daily
b) Once a week
c) Once a month
d) Quarterly

26) Vault and Cage Morgue merchandise is dead inventory and does not need to be counted.

True_____ False_____

27) The responsibility of verifying a customer license rests with:

a) The DEA
b) The Distribution Center
c) Corporate Headquarters
d) Regional Headquarters

28)You may sign a 222 narcotic order form if the customer gives you permission over the phone.

True_____ False_____

29) Cardinal Health, Inc. has a manual entitled *DEA Compliance Manual* which contains answers to frequently asked questions about controlled substance procedures.

True_____ False_____

30) List 5 things to look for when reviewing a 222 Narcotic Order Form:

_____
_____
_____

31) A customer calls your distribution center and asks you to fill an order involving one of his blanks but to send the controlled substances to another location. Is this a violation of the Code of Federal Regulations?

Yes_____ No_____

32) It is advisable that you use white-out or a pencil when working with DEA Form 222 (Narcotic Order Form) in case you make a mistake.

True_____ False_____

33) All visitors at your Distribution Center entering the cage or vault area must be escorted by an employee on the authorized access list?

True_____ False_____

Thank you for completing this test on the handling of controlled substances. Please return this test to your supervisor. He/She will send the test the Cardinal Health, Inc. Corporate Compliance Department in Dublin, Ohio for grading. Your Distribution Center Manager will be notified of your score as soon as your test is graded.

CardinalHealth

CONSENT AND RELEASE:

PLEASE READ THIS NOTICE AND CONSENT FORM CAREFULLY BEFORE SIGNING. YOU WILL BE PROVIDED WITH A COPY OF THIS FORM AT ANY TIME UPON REQUEST.

NOTICE AND CONSENT CONCERNING CONSUMER REPORTS FOR EMPLOYMENT APPLICATIONS AND EMPLOYMENT PURPOSES.

This form, which you should read carefully, has been provided to you because Cardinal Health ("Cardinal Health") will request consumer reports or investigate consumer reports in connection with your application for employment or during the course of your employment with Cardinal Health, if any. These background checks, and/or investigations, will be performed by Cardinal Health, in whole or in part, at Cardinal Health's discretion.

Cardinal Health's applicant background checks and employee investigations will also include the use of consumer reporting agencies to gather and report information to Cardinal Health in the form of consumer or investigative consumer reports, as regulated by federal law. Such reports, if obtained, will be prepared by consumer reporting agencies and may contain information concerning your credit standing or worthiness, character, general reputation, personal characteristics, or mode of living. Cardinal Health is not a consumer-reporting agency.

The type of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to; credit reports, criminal records (for the maximum period permitted by applicable state and federal law), court records, driving records, and/or summaries of educational and employment records and histories. The information contained in these reports may be obtained by a consumer reporting agency, from public records, or through personal interviews with co-workers, neighbors, friends, associates, current or former employers, or other personal acquaintances. Any information contained in such reports may be taken into consideration in evaluating your suitability for employment, promotion, reassignment or retention as an employee.

If Cardinal Health requests an investigative consumer report to be performed by a consumer reporting agency, as defined by federal law, you will receive a notice indicating that the report has been requested no later than three days after the request is made to the agency. This additional notice, if issued, will provide you with further information pertaining to federal law governing investigative consumer reports. You will not receive a notice if Cardinal Health or a person or entity other than a consumer-reporting agency performs the investigation.

Your consent is required by law before Cardinal Health may obtain a consumer report or investigative consumer report from a consumer reporting agency pertaining to your application for employment and thereafter, during the course of your employment, if any, at Cardinal Health's discretion. Your signature below indicates that you have read and understand that Cardinal Health may request and review a consumer report or investigative consumer report regarding your background, and that you consent to the release of reports to Cardinal Health for employment purposes. This information may also be considered for any future decisions concerning your employment, promotion, reassignment or retention as an employee of Cardinal Health. Your signature additionally reflects your understanding that such consent will remain in effect indefinitely until you revoke it in writing, as described below.

8.00

Refusal to consent to a consumer report or an investigative consumer report as required by this notice, or any other attempt to interfere or failure to cooperate with Cardinal Health's lawful investigation, may result in rejection of your application, withdrawal of an offer of employment, or corrective discipline; up to and including termination of employment.

CONSENT STATEMENT:

I have carefully read and understand this notice and consent form and, by my signature below, consent to the release of consumer or investigative consumer reports, as defined above, to Cardinal Health in conjunction with my application for employment. I further understand that this consent will apply during the course of my employment with Cardinal Health, should I obtain such employment, and that such consent will remain in effect until revoked in a written document signed by me.

In the event that I wish to refuse or revoke my consent, I understand that I may do so by: 1. Signing the "Refusal or Revocation of Consent Statement" below, or 2. Sending a signed statement, indicating that I revoke my consent for Cardinal Health to obtain a consumer report or investigative consumer report, and submitting to:

Cardinal Health
Human Resources
7000 Cardinal Place
Dublin, OH 43017

I certify that the information I have provided to Cardinal Health, on this consent and release form, is correct to the best of my knowledge and I understand that any falsifications, misrepresentations, and/or omissions may result in my disqualification for consideration of employment or, is subsequently employed, my dismissal.

Name of Applicant/Employee

Applicant/Employee Signature Today's Date

REFUSAL OR REVOCATION OF CONSENT STATEMENT:
(DO NOT SIGN UNLESS YOU HAVE DECIDED THAT YOU **WILL NOT** *CONSENT, OR WILL NO LONGER CONSENT, TO CARDINAL HEALTH OBTAINING A CONSUMER REPORT OR AN INVESTIGATIVE CONSUMER REPORT)*

I do not consent to Cardinal Health obtaining consumer reports or investigative consumer reports about me in connection with my application for employment or for any other employment purposes. If I have previously granted my consent, I hereby revoke that consent and understand that such revocation will take effect immediately after Cardinal Health receives this written revocation and has actual knowledge to communicate the revocation to those employees or agents who request consumer reports for Cardinal Health.

me of Applicant/Employee

Applicant/Employee Signature Today's Date

8.00

Education Verification

Institution/School	City	State	Dates Attended	Degree

Have you ever been convicted of a crime (felony or misdemeanor), or do you have any pending charges? * Yes ___ No ___

If yes, identify the crime, the date of the conviction, the court where the conviction occurred, and the disposition of the case. Please provide any details you feel are relevant. _____

_____

_____

Conviction of a crime will not automatically disqualify you from employment, but will be considered as a part of the overall evaluation of your qualifications for the position sought.

***ALABAMA, ARKANSAS, CONNECTICUT, HAWAII, IDAHO, KANSAS, MAIN, MARYLAND, MINNESOTA, NEW JERSEY, OKLAHOMA, SOUTH CAROLINA, TENNESSEE VIRGINIA, WEST VIRGINIA, WYOMING RESIDENTS:** Do not include information regarding juvenile records.
ALASKA RESIDENTS: Do not include information for convictions more than 10 years old. Do not include information on pending arrests greater than 1 year old.
CALIFORNIA RESIDENTS: Do not include misdemeanor convictions for which you have successfully completed probation or that have been otherwise discharged. Do not include information regarding referral to/participation in a pre or post trial diversion program. Do not include information regarding convictions for marijuana-related offenses greater than two years old.
GEORGIA RESIDENTS: Do not include information regarding juvenile records, unless you have more than one offense as a juvenile.
INDIANA RESIDENTS: Do not include information convictions for misdemeanors or summary offenses.
MASSACHUSETTS RESIDENTS: You may respond no concerning: an arrest, detention or disposition regarding any violation of law in which no conviction resulted; a first conviction for any of the following misdemeanors - drunkness,simple assault, speeding, minor traffic violations, affray, or disturbance of the peace; or any conviction of a misdemeanor where the date of such conviction or the completion of any period of incarceration resulting therefrom. Whichever date is later, occurred five or more years prior to today's date, unless you have been convicted of any offense with five years immediately preceding today's date. Do not include information regarding general misdemeanors or juvenile records. Include information regarding drug offenses, unless otherwise excluded above. An applicant for employment with a sealed record on file with the commissioner of probation may respond "no record" to any inquiry herein relative to prior arrests or criminal court appearances.
MICHIGAN RESIDENTS: Do not include information regarding pending misdemeanor charges.
MONTANA RESIDENTS: Do not include information regarding misdemeanor convictions or deferred prosecutions.
NEBRASKA RESIDENTS: Do not include information concerning pending arrests greater than one year old and where active prosecution in not contemplated or pending.
NEW HAMPSHIRE RESIDENTS: Only include information for the last five years.
OREGON RESIDENTS: Do not include pending arrest information greater than one year old.
PENNSYLVANIA RESIDENTS: Do not include information regarding pending arrests greater than three years old.
UTAH RESIDENTS: Do not include information regarding misdemeanor convictions.
WASHINGTON RESIDENTS: Do not include information greater than seven years old.

Waiver: I hereby authorize Cardinal Health, its subsidiaries or affiliates, and the Drug Enforcement Administration to make a complete investigation of me, my former business relations and employment, and any business organization or any other person to give full information and records about me. I hereby release Cardinal Health its subsidiaries, affiliates, officers, employees, informants and the Drug Enforcement Administration from liability arising from this investigation. Discovery of false information on this sheet may lead to discharge of my employment with Cardinal Health or its subsidiaries or affiliates.

FA08.00

Signature _____ Today's Date _____

1/02

CardinalHealth

SECURITY INFORMATION FORM

Submitted ___/___/____

Division:_____ Supervisor:_____

Department:_____ Date of Hire_____

Name:_____ (First) (Middle) (Last)

Present Address:

_____ (Street) (City) (State) (Zip)

Time at residence:_____ County of Residence:_____ Telephone: ( )_____

Previous Name_____ (First) (Middle) (Last)

Previous Residence

_____ (Street) (City) (State) (Zip)

Time at previous residence_____ County of previous residence_____

Social Security Number_____ **Drivers License Number**_____ **State**_____

Date of Birth_____ Place of Birth_____ **Gender**_____

FA08.00

1/02

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

DEA09.00

TITLE: DEA Inspections

ISSUE DATE: 6-15-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA09.00**
TITLE: DEA Inspections	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA and Cardinal Health, Inc. requirements for DEA regulatory inspections and to provide guidance for distribution center management.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Upon notice of a DEA inspection, the facility must contact the Corporate Compliance Department immediately and provide the following information:

   a.) The nature of the visit.

   b.) The names of the inspectors.

2.) Upon arrival of the investigators at the facility, the manager, his/her designated alternate and/or the individual who has overall responsibility for controlled substances shall meet with investigators and do the following:

   a.) Review their credentials (picture of person on an official ID card).

   b.) Accept the DEA Notice of Inspection (DEA Form 82 – **Exhibit EA09.00**).

3.) If there is any question as to the identity of the inspector, management shall not allow access to the facility until the following verification steps are taken:

   a.) Request the name and phone number of their immediate supervisor.

   b.) Contact the investigator's supervisor for verification.

   c.) If the facility cannot obtain verification, contact the Corporate Compliance Department for assistance.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA09.00**
TITLE: DEA Inspections	**ISSUE DATE:** **PAGE:** 3 of 5

4.) Inspectors shall be asked to sign the visitor's log and wear a visitor badge at all times while on the company premises.

5.) Management shall engage in a discussion with the inspector regarding the following:

a.) The purpose and extent of the investigation.

b.) Desire of management for a close-out discussion at the completion of the investigation.

6.) The facility shall give full cooperation to the inspecting authorities.

7.) The facility must maintain a complete and current DEA On-site Background Information Package (**Form FA09.00**) which shall be used to provide the DEA Inspectors with pertinent company information.

8.) Only persons authorized by management shall answer questions posed by investigators.

9.) Inspections must be closely monitored by qualified personnel. The individual shall be prepared to:

a.) Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the area.

b.) Explain the operation/type of security, record keeping and reporting systems/procedures maintained.

c.) Assist the investigators.

d.) Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of records reviewed.

e.) Obtain copies for and retain copies of any documents the investigators requested.

f.) Assure that information volunteered is clearly beneficial to the facility.

g.) Assure no misrepresentations are given to the investigators.

h.) Note any suggestions or criticisms expressed by the investigators and immediately correct and document any violations discovered in this manner.

i.) Complete a daily detailed written record of the inspection which includes the following:

i.) Any question raised by the inspector.

ii.) Any question raised by the monitor.

iii.) Any request made by the inspector.

iv.) What the inspector was shown.

v.) A list of any records viewed or copied by the inspector.

vi.) Items inventoried and verification of inspector's counts.

vii.) Any suggestions of criticisms expressed by the inspector.

10.) Once aware of any violations, the facility shall take the following initiatives in seeking and implementing corrective actions:

a.) Reconstruct the investigation and findings by using the same documents, facility review utilized by the investigator and the internal report prepared by the facility.

b.) Take appropriate action to correct any violations or problems uncovered during the investigation.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **DEA09.00**
TITLE: DEA Inspections	**ISSUE DATE:**
	PAGE: 5 of 5

c.) Convey to DEA the corrective action taken, what steps the facility has taken to prevent future problems and inquire whether further action is necessary.

11.) At the conclusion of the investigation, the facility must complete the DEA Inspection Report (**Form FB09.00**) and forward it to the Corporate Compliance Department.

Reference: **Exhibit EB09.00 Inspection Do's and Don't's**
Exhibit EC09.00 Distributor Accountability Investigation Procedures

FA09.00

DEA ON-SITE BACKGROUND INFORMATION PACKAGE

SECTION I FIRM'S BACKGROUND

A.. **Company Name:** _____

Address: _____

Telephone Number: (____) _____

Fax Number: (____) _____

B. **Type of Firm:** _____

C. **Corporate Headquarters:** _____

D. **State of Incorporation:** _____

E. **Subsidiaries:** _____

F. **Corporate Officers: (Obtain current copy from Corporate Compliance)**

G. **Principle Management Personnel:**
(List all personnel and include the following information)

Name: _____
Title: _____
Length of Service: _____

H. **Type of Business:** _____

I. **Distribution Area:** _____

J. **Methods of Distribution (Delivery Companies):** _____

K. **Hours of Operation:** _____

L. **Number of Employees:** _____

M. **How long at present location:** _____

N. **Controlled substance sales as percentage of total sales:** _____

SECTION II **LICENSES AND REGISTRATIONS**
(attach copies of DEA registration and State licenses).

A. **DEA (See attached):**

B. **State (See attached):**

SECTION III
(Breifly describe when inventories are taken and where records are maintained).

A. **Biennial Inventories:** _____

B. **Periodic Inventories:** _____

SECTION IV **RECORDS / REPORTS**
(briefly describe the types of records and where maintained)

A. **Purchase Records:** _____

B. **Sales Records:** _____

C. **Return Records:** _____

D. **DEA Form 222 - (blue & brown):** _____

E. **Power of Attorney:**

F. **DEA Form 106:**

G. **DEA Form 41:**

H. **ARCOS Records:**

I. **Suspicious/Excessive Customer Purchases:**

J. **Customer DEA Registrations and Verifications:**

SECTION V **PROCEDURES**

(Briefly describe how the following is accomplished with respect to controlled substances).

A. **Receiving:** _____

B. **Order Filling:** _____

C. **Shipping:** _____

D. **Returns:** _____

SECTION VI **SECURITY**

A. **Structure of Building:** _____

B. **Structure of Vault:** _____

C. **Structure of Cage:** _____

D. **Alarm Company:** _____
Address: _____

E. **Type of Alarm Hardware:** _____

F. **Type of Circuit (McCulloh Loop, etc.):** _____

G. **Notification Procedures:** _____

_____
_____
_____

H. **Who Responds:** _____

I. **Response Time:**

Alarm Company: _____
Law Enforcement: _____
Distribution Center Personnel: _____

J. **Persons with Alarm Keys/Passes:**
(List all personnel and include the following information):

Name: _____ **Title** _____
Length of Service: _____

K. **Persons with Access to Vault:**
(List all personnel and include the following information)

Name: _____ **Title** _____
Date of Birth: _____ **SS#** _____

L. **Persons with Access to Cage:**
(List all personnel and include the following information)

Name: _____ **Title** _____
Date of Birth: _____ **SS#** _____

M. **Employee Screening procedures (Describe hiring practices):**

_____
_____
_____
_____
_____

Cardinal Health Pharmaceutical Distribution: DEA Registered Locations

Distribution Center	*Address*	*DEA Number*
Cardinal Health	500 Jerry Steele Lane McDonough, GA 30253	RC0271267
Cardinal Health	801 C St. NW, Suite B Auburn, WA 98001	RW0191813
Cardinal Health	2353 Prospect Dr. Aurora, IL 60504	RW0231908
Cardinal Health	11 Centennial Drive Peabody, MA 01960	RD0108200
Cardinal Health	15 Ingram Blvd. LaVergne, TN 37086	RC0229965
Cardinal Health	14601 County Road 212 Findlay, OH 45840	RC0313940
Cardinal Health	4875 Florence Street Denver, CO 80238	RW0263549
Cardinal Health	4 Cardinal Health Ct. Greensboro, NC 27407	RW0243903
Cardinal Health	13651 Dublin Ct. Stafford, TX 77477	RC0333524
Cardinal Health	2901 Enloe St. Hudson, WI 54106	RW0243725

Distribution Center	*Address*	*DEA Number*
Cardinal Health	1240 Gluckstadt Road Madison, MS 39110	RC0221236
Cardinal Health	7601 NE Gardner Avenue Kansas City, MO 64120	RW0191926
Cardinal Health	2512 West Cott Blvd. Knoxville, TN 37931	RC0238104
Cardinal Health	2045 Interstate Drive Lakeland, FL 33805	RC0182080
Cardinal Health	401 Mason Rd. LaVergne, TN 37086	RN0281054
Cardinal Health (NLC)	5995 Commerce Center Dr. Groveport, OH 43125	RC0314891
Cardinal Health	3450 East Pike Zanesville, OH 43701	RN0209583
Cardinal Health	850 Airport Distribution Dr. Zanesville, OH 43701	RN0231427
Cardinal Health	1120 Commerce Blvd. Swedesboro, NJ 08085	RW0269654
Cardinal Health	600 N 83rd Avenue Tolleson, AZ 85353	RW0263056
Cardinal Health	3238 Dwight Road Elk Grove, CA 95758	RW0236009

Distribution Center	*Address*	*DEA Number*
Cardinal Health	955 West 3100 South S. Salt Lake City, UT 84119	RW0191419
Cardinal Health	2840 Elm Point Industrial Dr. St. Charles, MO 63301	RW0283452
Cardinal Health	6012 Molloy Rd. Syracuse, NY 13211	PC0003044
Cardinal Health	27680 Avenue Mentry Valencia, CA 91355	RW0216449
Cardinal Health	71 Mil-Acres Dr. Wheeling, WV 26003	RO0153609
Cardinal Health	851 Henrietta Creek Rd. Roanoke, TX 76262	RW0279996

FB09.00

DEA INSPECTION REPORT

This form is to be completed by the Division Manager or his designee and forwarded to the Corporate Compliance Department upon completion of a DEA inspection.

DIVISION: _____ DATE: _____

A. General Information

1. Initiation Date _____
2. Leader Compliance Investigator _____
3. DEA Office _____
4. Closing Date -- Exit Interview _____
5. Total On-Site Days _____
6. Total On-Site Person Hours _____

B. Inventory Accountability Audit

1. Number of items audited _____

a) Description and class of items audited:

2. Audit timeframe in months _____
3. Number of items in variance _____

C. **Inspection Focal Points (Check all that apply)**

1. Background information ☐
2. Biennial Inventory ☐
3. Recordkeeping ☐
4. DEA Form 222 ☐
5. Physical Security ☐
6. Procedural Security ☐
7. Shipping/Receiving Procedures ☐
8. Registration Verification/Customers ☐
9. ARCOS ☐
10. Suspicious Order Monitoring ☐
11. Destructions ☐
12. Losses/Thefts ☐
13. Pre-Employment Screening ☐
14. Will Calls ☐
15. Powers of Attorney ☐
16. Other _____ ☐

D. **Comments**

Please document any significant comments, questions, criticisms made by the inspector during the inspection and exit interview and attach to this report.

E. **Resolution (to be completed by Corporate Compliance Department)**
Please attach all related documentation.

1.	DEA Follow-Up	*Yes* ☐	*No* ☐	
2.	DEA Letter of Admonition	*Yes* ☐	*No* ☐	
3.	DEA Citation	*Yes* ☐	*No* ☐	
4.	Memorandum of Understanding	*Yes* ☐	*No* ☐	
5.	Informal Hearing	*Yes* ☐	*No* ☐	
6.	Formal Hearing	*Yes* ☐	*No* ☐	
7.	Court Proceeding	*Yes* ☐	*No* ☐	
8.	Consent Order	*Yes* ☐	*No* ☐	
9.	Total Violations Acknowledged in M.O.U.			
10.	Fines Sought			$ _____
11.	Fines Paid			$ _____
12.	Resolution Date			_____

_____ _____
Signature and Title of Person Completing Form Date

_____ _____
Division Manager's Signature Date

FOIA Confidential Treatment Requested By Cardinal

CAH 022273

Corporate Inspection Guidelines
Inspection Dos and Don'ts

- Receptionists must know whom to call when a regulatory agency inspector visits.
- Determine that an inspector is legitimate by examining his/her credentials.
- Require the inspector to sign in and wear a visitor's badge.
- Contact Corporate Compliance
- Receptionists or initial contact persons must inform all key employees that an inspector is present.
- Someone, but not a large number of individuals, must accompany the investigator and be with the investigator at all times.
- If the inspector is not familiar with the facility, describe the operations before entering the warehouse/production areas.
- At the beginning, review with the inspector all company policies and programs.
- Do not start an argument with, get intense with or lie to the inspector.
- Employees must be cooperative and seek to avoid conflict. Base discussions on the laws, regulations, guidances, etc.
- Understand the inspector's questions before answering. If needed, ask for an explanation. Refer each question to the most suitable employee.
- Answer only the question asked. Do not offer additional information unless it will benefit the company.
- Do not sign any affidavits without Legal department approval.
- Be sensitive to the compliance role of the inspector; do not threaten to call his/her supervisor when the inspector is doing his/her job.
- Deficiencies noted by the inspector must be corrected as soon as possible.
- Keep a detailed written record of the inspection.
- Keep duplicate copies of records/materials given to the inspector.
- During the exit interview, make sure that all deficiencies are adequately discussed. If there is disagreement, present all of the company information and any regulations and official interpretations that support the company's viewpoint.
- Submit a detailed written record of the inspection to Corporate Compliance.

DISTRIBUTOR ACCOUNTABILITY INVESTIGATIONS PROCEDURES

An investigation is divided into four phases: preparation, on-site, follow-up and past history. The information sought by the DEA during each phase is outlined below.

Preparation

Prior to inspecting a facility, the registrant files at the respective DEA location are reviewed; i.e., review of ARCOS reports, review of registration categories and schedules, etc.

On-Site Investigation

Initial Phase

The initial phase involves initial discussion, presentation of investigator credentials and notice of inspection (if a warrant is used, the registrant must consider the need for an attorney). The credentials and notice will be presented to that person who has managerial responsibility for operating the firm. The investigator must state the purpose and indicate the scope of the investigation.

Management at this time shall request that the investigators advise them of any violations discovered during the investigation so that corrective action can be taken immediately. Management shall state that they desire a closing discussion at the completion of the investigation.

Background Information

The DEA investigators will want to know the:

- Names, addresses, date of birth and social security numbers of corporate officers and/or owners of the registrant and identification of individuals responsible for record keeping and security;
- Number of employees and appropriate registration (federal, state and local); and
- Percentage of business dedicated to controlled substances.

They also will want to review reporting procedures regarding thefts, losses or destruction of controlled substances.

A completed copy of the **DEA On-site Background Information Package** can provide the DEA Inspectors with pertinent company information.

Closing Inventory

The closing inventory is usually taken before or after business hours, so that no adjustments for transactions outside the accountability period are necessary. An accurate inventory is necessary and advantageous. All shipping, receiving and return areas, as well as other areas where controlled substances might be stored, must be checked.

A responsible employee of the registrant must verify the accuracy of the inventory and make a copy for the registrant's records.

Initial Inventory

An actual inventory taken by the registrant, an inventory from a previous DEA investigation or a computer inventory printout may be utilized if the registrant will attest to its accuracy.

Regardless of the inventory used, the required biennial inventory will be reviewed.

Receiving Records

Order forms will serve as the primary record of documenting the receipt of Schedule II controlled substances. They also will be reviewed for accuracy.

The power of attorney will be reviewed.

ARCOS reports and purchase invoices will be reviewed to verify accuracy of the order form transactions for Schedule II controlled substances and Schedule III narcotic controlled substances.

Receiving records which record supplier's name, address, and DEA number; name of controlled substance; strength; quantity received; and date of receipt for Schedule III through Schedule V will be reviewed. These records must be kept in a readily retrievable manner. The registrant will be required to attest to the accuracy of the records.

Sales Records

Order forms will serve as the primary record documenting the sale of Schedule II controlled substances. They also will be reviewed for accuracy.

Registration of customers will be verified.

A sampling of ARCOS records and customer sales records for Schedule II controlled substances and Schedule III narcotic controlled substances will be reviewed to verify shipments.

The quantity of Schedule III through Schedule V controlled substances distributed may be determined from a number of different types of records. The primary record is the distributor's sales invoice.

Sales will include all dispositions from inventory, including documented and reported thefts, returns and destructions.

Credits and Returns

A review of credit memoranda will be made to determine that there was physical movement of controlled substances or credit.

Returned controlled substances will be inspected to verify that there is documentation showing returns, disposition by destruction or return to inventory.

Note: If the registrant has another record keeping system, such as the computerized Selected Item Audit Report which contains all required information and attests to its accuracy, these records may and should be used.

ARCOS

Reports will be verified by comparing them to other purchase and sales records.

Accountability

The initial inventory is combined with all receipts (including returns) of controlled substances and compared to the closing inventory plus sales, destructions, returns, reported thefts or losses accounted for by the registrant from its records.

Security

This evaluation will include:

- Review of location, crime classification, building construction, access restrictions and storage areas, including size and type of physical security systems in place;
- Evaluation of alarm systems and test;
- Review of security and procedures employed in shipping and receiving areas, picking areas, and packaging areas;
- Review of procedures for determining proper registration of customers;
- Review of frequency of alarm checks and procedures for key control, after hours entry, badge system and lock changing; and
- A review of the registrant's system for monitoring unusual and excessive orders.

Discussion with Management

This will be used to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them, or the registrant's challenge of the findings by nonacceptance of the violations. If DEA's intention is to take further action, the

registrant may be informed of courses of action possible, but not the specific action to be recommended.

*Note: DEA is **not required** to conduct a closing discussion at the completion of the investigation. In this case, the registrant shall request a closing discussion at the convenience of the investigator. If the request is not successful, it is suggested that the registrant send a written request to the investigator's supervisor, expressing the desire for a meeting to discuss any findings and corrective action which may be required.*

Follow-Up Investigation

After the on-site portion of the investigation is completed, a verification of purchases and sales most likely will be performed. The extent of the verification will depend upon the nature of the investigation and discrepancies found. In addition, DEA may conduct file checks on all persons who are interviewed during the investigation.

History of Violations

The registrant's history if violations will be taken into consideration by DEA in determining the type of action to be levied against the registrant.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA00.00

TITLE: State License Requirements

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA00.00**
TITLE: State License Requirements	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with the FDA and state licensing authority requirements for the licensing of wholesale drug distributors.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility must obtain and maintain a current valid state license or licenses from the state licensing authority where the distribution center is located.

2.) The facility must obtain and maintain a current valid state license or licenses, if required, for each state into which they ship prescription drugs.

3.) The facility must obtain and maintain current valid state licenses for intra-company transfer activity when shipping to other Cardinal Health facilities in Arizona, Colorado, Iowa, Michigan, Missouri, Ohio and Wyoming.

Reference: Exhibit EA00.00 PDMA Guidelines for State Licensing of Wholesale Prescription Drug Distributors.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.1]

[Page 95]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.1 Scope.

This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale distribution of human prescription drugs in interstate commerce.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.2]

[Page 95]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.3]

[Page 95-96]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.3 Definitions.

(a) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) Blood component means that part of blood separated by physical or mechanical means.

(c) Drug sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) Prescription drug means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) Wholesale distribution and wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, emergency medical reasons includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with Sec. 203.23 of this

chapter; or
(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.
(g) Wholesale distributor means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale

[[Page 96]]

drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.
(h) Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a ``health care entity'' and a retail pharmacy or wholesale distributor.

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67762, Dec. 3, 1999]

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.4]

[Page 96]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.5]

[Page 96]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.5 Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in Sec. 205.4 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

(Approved by the Office of Management and Budget under control number 0910-0251)

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.6]

[Page 96-97]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.6 Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

[[Page 97]]

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.7]

[Page 97]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.7 Personnel.

The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.8]

[Page 97]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR205.50]

[Page 97-99]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 205--GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR

Sec. 205.50 Minimum requirements for the storage and handling of prescription drug records.

The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. (1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at ``controlled'' room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) Examination of materials. (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance

[[Page 98]]

of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs. (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Recordkeeping. (1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days

of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

[[Page 99]]

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Compliance with Federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

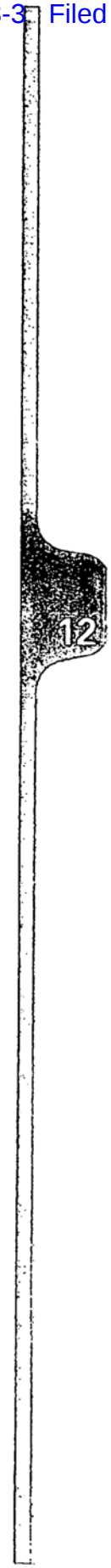
(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Approved by the Office of Management and Budget under control number 0910-0251)

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67763, Dec. 3, 1999]



CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA01.00**
TITLE: Personnel	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 3
RESPONSIBILITIES:	
APPROVALS:	

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs